Supreme Court, U.S.
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NO. _____

IN THE
SUPREME COURT OF THE UNITED STATES

TERENCE J. SCALLEN., *Petitioner*
AND,
GALEN D. KNIGHT, *Petitioner*
vs.
THE REGENTS OF THE UNIVERSITY
OF NEW MEXICO, *Respondent.*

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

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PETITION FOR WRIT OF CERTIORARI

Terence J. Scallen, M.D., Ph.D., *Pro Se*
PO. Box 651
Borrego Springs, CA 92004-0651
Telephone: 760-767-3444

and

Galen D. Knight, Ph.D., *Pro Se*
3205 Arizona NE
Albuquerque, NM 87110

ORIGINAL

QUESTIONS PRESENTED

1. Did the Federal Circuit ignore its own precedent and the clear precedent of this Court in failing to recognize that the 1983 University of New Mexico (UNM) Patent Policy misrepresents established law by asserting UNM to be the *initial* owner of employee inventions, without any requirement for inventor assignment, in violation of the Constitution, Article I, § 8, Clause 8?

2. Are inventor assignments demanded by UNM on the basis of this misrepresentation of law invalid?

3. Can UNM, claiming ownership of patents and applications, lawfully make fundamental changes in the content of those applications without authorization from, and over the strenuous objections of, the inventors?

4. Does the consequent publication by UNM of patents in the inventors' names, containing the unauthorized changes referred to in 3) above (changes which the inventors know to be wrong), violate the inventors' right to free speech, more specifically their academic freedom under the First Amendment?

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Petitioners are Terence J. Scallen, M.D., Ph.D., *Pro Se*, and Galen D. Knight, Ph.D, *Pro Se*. Petitioners are defendants in the district court (*Regents of the Univ. of N.M. v. Knight*, No. CIV 99-577) and appellants in the Court of Appeals for the Federal Circuit (*Regents of the University of New Mexico v. Knight*, 02-1018, -1019). Respondent is The Regents of the University of New Mexico. Respondent is the plaintiff in the district court and appellee in the Court of Appeals for the Federal Circuit.

Pursuant to Rule 29.6, Petitioners state that both Terence J. Scallen and Galen D. Knight are individuals and represent themselves. There are no corporate interests for either Petitioner.

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TEXT OF CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

Constitution

1. **Constitution, Article I, § 8, Clause 8:**

   "The Congress shall have power ... to promote progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries:"

2. **Constitution, First Amendment:**

   "Congress shall make no law ... abridging the freedom of speech or of the press;"

Statutes

1. **35 U.S.C. § 111. Application:**

   " (a) In general. (1) Written application. An application for patent shall be made, or authorized to be made, by the inventor ... ."

   "(2) Contents. Such application shall include- a specification as prescribed by section 112 of this title; a drawing as prescribed by section 113 of this title; and an oath by the applicant as prescribed by section 115 of this title."

2. **35 U.S.C. § 115. Oath of Applicant:**

   "The applicant shall make oath that he believes himself to be the original and first inventor of the process, machine, manufacture, or composition of matter or improvement, for which he solicits a patent:"

3. **35 U.S.C. §132. Notice of rejection; reexamination; (a), sentence 2:**

   "No amendment shall introduce new matter into the disclosure of the invention."

Regulations

1. **37 C.F.R. § 1.63(b) and § 1.63(b)(1); Oath or declaration:**

   "(b) In addition to meeting the requirements of paragraph (a), the oath or declaration must state that the person making the oath or declaration:

   (1) Has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration."

2. **37 C.F.R. § 1.67(c), Supplemental oath or declaration:**

   "(c) A supplemental oath or declaration meeting the requirements of § 1.63 must also be filed if the application was altered after the oath or declaration was signed or if the oath or declaration was signed:

   (1) In blank;

   (2) Without review thereof by the person making the oath or declaration; or

   (3) Without review of the specifications, including the claims, as required by § 1.63(b)(1).

PETITION FOR CERTIORARI

Petitioners Terence J. Scallen, M.D., Ph.D., *Pro Se*, and Galen D. Knight, Ph.D., *Pro Se*, respectfully pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Federal Circuit entered in this proceeding on the 28th day of February 2003.

OPINIONS BELOW

The opinion of the Court of Appeals for the Federal Circuit, *Regents of University of New Mexico v. Knight*, (App. A1-27) is reported at 321 F.3d 1111 (Fed. Cir. 2003). The rulings of the district court are unreported (App. A28-49).

JURISDICTION

The judgment of the Court of Appeals for the Federal Circuit was entered on February 28, 2003. Scallen's Petition for Rehearing *En Banc* and Knight's Petition for Panel Rehearing were both timely filed (March 12 and March 14, 2003, respectively). The Court of Appeals denied both petitions for rehearing on April 3, 2003.

The original jurisdiction of the district court was pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201, and the Patent Laws of the United States, Title 35 of the United States Code; the district court had supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

Constitution

1. Article I, § 8, Clause 8
2. First Amendment

Statutes

1. 35 U.S.C. § 111 (1994)
2. 35 U.S.C. § 115 (1994)
3. 35 U.S.C. § 132(a), sentence 2 (1994)

Regulations

1. 37 C.F.R. § 1.63(b) and § 1.63(b)(1) (1994)
2. 37 C.F.R. § 1.67(c) (1994)

STATEMENT OF THE CASE

I. Statement of Facts

Scallen was Professor of Biochemistry and Professor of Medicine at the University of New Mexico (UNM). In 1983 when Knight joined Scallen's laboratory as a postdoctoral associate there was a convergence of ideas, findings, and interests from both Knight and Scallen which led to the theoretical postulation of key small regulatory sulfur-containing molecules, related to components of Coenzyme A, which would be capable of regulating multiple cellular metabolic pathways in an *integrated* manner. Experiments were conducted which led to the verification of this hypothesis and which, therefore, led to the vitaletheine modulator and beta-alethine inventions. Regarding beta-alethine, Dr. Paul Mann (hereinafter "Mann") was of great assistance in evaluating these ideas using cultured cells.

By 1986 the inventions had been essentially completed and reduced to practice. On October 31, 1986 an invention disclosure letter was written by the inventors to Dean

Napolitano, Director of the UNM Medical Center. Patent preparation was well under way by June of 1987.

On July 6, 1990 five U.S. patent applications were filed:

1. 07/549,438 Galen D Knight and Terence J. Scallen, *Vitaletheine Modulators and Use in Cell Cultures;*

2. 07/549,105 Galen D. Knight and Terence J. Scallen, *Vitaletheine Modulators in the Prophylaxis and Treatment of Disease;*

3. 07/549,440 Galen D. Knight and Terence J. Scallen, *Therapeutic Use of Vitaletheine Modulators in Neoplasia;*

4. 07/549,104 Galen D. Knight, Paul L. Mann, and Terence J. Scallen, *Beta-alethine Use in Cell Culture and Therapy;*

5. 07/549,103 Galen D. Knight, Paul L. Mann, and Terence J. Scallen, *Beta-alethine As Anti-tumor Agent.*

All five of these original 1990 U.S. patent applications have been abandoned.

Although there is no mention of assignment by inventors in UNM's 1983 Patent Policy (App. A55-58), UNM claimed it was legally entitled to assignment and demanded that Knight and Scallen assign. Because of this claim and these demands Knight and Scallen submitted, and signed assignments (*e.g.*, App. A59-60) for the five 1990 patent applications in 1991.

Five continuation-in part (CIP) applications, containing new experiments (new matter) not present in the 1990 applications, were filed in 1992 in place of each of the 1990 applications and were authorized by Knight and Scallen. Knight and Scallen executed inventor declarations and power of attorney documents for each of the five 1992 CIP

applications. UNM noticed it had no assignment of the 1992 CIP applications in July of 1995, but did not demand same until 1996. Both Knight and Scallen refused.

U.S. Patent 5,370,868 (hereinafter the "'868 patent"), Galen D. Knight and Terence J. Scallen, *Therapeutic Use of Vitaletheine Modulators in Neoplasia*, issued directly from one of the 1992 CIP applications (07/928,725), December 6, 1994, and was authorized by the inventors, Knight and Scallen. This is a patent for the *use* of the vitaletheine modulators in the treatment of neoplasia; it does not claim patent *compound* coverage.

On November 1, 1994 Knight, Scallen, and other collaborating scientists published two articles in *Cancer Research*:

- Knight, G. D., Laubscher, K. H., Fore, M. L., Clark, D. A., and Scallen, T. J. "Vitalethine Modulates Erythropoiesis and Neoplasia", *Cancer Res.* 54, 5623-5635 (1994).
- Knight, G. D., Mann, P. L., Laubscher, K. L., and Scallen, T. J. "The Seemingly Diverse Activities of ß-Alethine", *Cancer Res.* 54, 5636-5642 (1994).

On August 23, 1994 UNM licensed the Knight and Scallen (and Knight, Mann, and Scallen) inventions, patents and applications to Dovetail Technologies, Inc. (Floyd Taub hereinafter "Taub").

In September of 1994 new attorneys (Nixon & Vanderhye), without power of attorney from Knight and Scallen, assumed patent prosecution of the applications.

In 1995-1996 UNM amended various vitaletheine modulator applications without the *prior* knowledge or consent of Knight and Scallen. These amendments changed the compound structures of two of the vitaletheine modulator compounds to structures of different compounds (taurines), i.e., the benzyl derivative (sulfenate-linked benzyl

carbamate dimer) of the vitaletheine compound was changed to carbobenzoxy-beta-alanyl-taurine and vitaletheine V_4 to beta-alanyl-taurine. These taurine compounds were synthesized by Murray and Wallace [agents of Taub (the licensee) and UNM] using synthetic methods different from those taught by Knight and Scallen in the '868 patent. Compound and utility coverage for a third compound, vitalethine, taught in the 1992 CIP applications and in the '868 patent, was deleted by UNM.

These unauthorized amendments gave rise to three unauthorized patents, containing the substituted compounds (taurines):

- U.S. 5,578,313 Galen D. Knight and Terence J. Scallen, *Therapeutic Use of Vitaletheine Modulators in Neoplasia*, issued November 26, 1996;
- U.S. 6,096,536 Galen D. Knight and Terence J. Scallen, *In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine or Carbobenzoxy-Beta-Alanyl-Taurine*, issued August 1, 2000;
- U.S. 6,323,025 Galen D. Knight and Terence J. Scallen, *In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine or Carbobenzoxy-Beta-Alanyl-Taurine*, issued November 27, 2001.

In June of 1996, after learning of the changed compound structures contained in a Murray declaration (agent of the licensee), Scallen protested to UNM. *See* App. A80-82. Knight also protested.

On May 20, 1996 Quintana, UNM patent administrator at the time, submitted a document to the Patent Office claiming full right, title, and interest in the vitaletheine modulator applications derived from the 1992 CIPs. However, it is undisputed that UNM did/does not have assignments of the five 1992 CIP applications and their progeny.

On November 26, 1996 U.S. Patent 5,578,313 (hereinafter the '"313 patent") issued. This patent contained the structures of the *changed* compounds in both the specifications and the claims, improperly using the *same* chemical and physical characterization data (data which is *inconsistent* with the chemical nature of the substituted compounds) and also improperly using the *same* biological efficacy data which had been obtained *earlier* by Knight and Scallen using the *original* compounds (as reported previously in the '868 patent).

The inventor declaration contained in the '313 patent file wrapper (App. A75-79) was the *same* inventor declaration contained in the earlier '868 patent file wrapper (App. A68-72), signed by Knight and Scallen on August 10, 1992, swearing to the accuracy of the *1992 CIP applications* containing the original vitaletheine modulator compounds *which resulted in the '868 patent.*

In early 1997 when Knight and Scallen first learned of the issuance of the '313 patent containing these fundamental and unauthorized compound changes, the inventors protested [to Quintana, UNM patent administrator; to Estes, UNM council, App. A83-86; and to the Patent Office] the erroneous changes contained in the '313 patent. In spite of Knight and Scallen's protests UNM took no steps to correct the erroneous changes in the '313 patent. Instead, UNM caused to issue two additional patents (deleting vitalethine and substituting the same two erroneous taurine compounds) as referred to above, *i.e.*, U.S. 6,096,536 and 6,323,025.

UNM has also made unauthorized changes to the claims in the beta-alethine patents, *i.e.*, U.S. 5,643,966, 6,046,241, and 6,245,561.

Since the licensing of the inventions in 1994 Knight and Scallen have been prevented from participating in any way in the patenting process, such as the review and signing of

papers required by the Patent Office in the filing of patents and applications.

II. Proceedings Below

A. Proceedings Before the District Court

On May 21, 1999 UNM filed suit against Knight and Scallen. The complaint (and amended complaint) contained seven counts:

> *Count I* Declaration of Ownership of the Vitaletheine Patents, Patent Applications and Trade Secrets;
>
> *Count II* Declaration of Ownership of the Beta-Alethine Patents, Patent Applications and Trade Secrets;
>
> *Count III* Determination and Correction of Inventorship of Patents;
>
> *Count IV* Breach of Contract;
>
> *Count V* Intentional Interference With Existing Contractual Relations;
>
> *Count VI* Conversion, or in the Alternative, Replevin;
>
> *Count VII* Slander of Title.

Knight and Scallen each filed separate answers and asserted counterclaims.

The district court declared the 1983 UNM Patent Policy the controlling patent policy in this case (March 21, 2000). [1] Scallen then submitted a motion (June 21, 2000) for a declaration by the court that UNM's claim of ownership in the 1983 Patent Policy is invalid. Scallen also submitted a motion (July 3, 2000) for a declaration by the court that the

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[1] Both UNM's complaint and its amended complaint contained a different and more recent " Intellectual Property Policy" which the district court determined was not applicable.

five 1991 assignments by Knight and Scallen are invalid. On January 29, 2001 the district court denied both of these motions, providing no legal analysis.

Scallen asserted that the amendments inserted by UNM, over the objections of the inventors, were/are a violation of his academic freedom (*Doc.* 101, filed March 15, 2000). Knight also raised this issue.

On August 9, 2000 the district court granted summary judgment (Count II) in UNM's favor, declaring UNM the owner of the beta-alethine patents and applications. On January 29, 2001 the district court also granted summary judgment (Count IV, breach of contract) in UNM's favor, as to both the beta-alethine and the vitaletheine patents and applications.

Further, on June 19, 2001 the district court granted UNM's motion to dismiss *with prejudice* Counts V, VI and VII of its amended complaint.

Beginning on June 25, 2001 a four-day bench trial was conducted. The only issue considered was whether or not new matter was introduced when UNM amended certain vitaletheine modulator applications, deleting compound and utility coverage for vitalethine and changing the compound structures of two other vitaletheine modulators taught in U.S. Patent 5,370,868. Three patents, U.S. 5,578,313, 6,096,536 and 6,323,025, have issued incorporating these fundamental changes in compound structures, changes made by UNM over the strenuous objections of the inventors, Knight and Scallen.

On September 10, 2001 the district court submitted its findings of fact and conclusions of law (App. A28-44) and final order (App. A45-49) and declared a) UNM to be the owner of the vitaletheine modulator patents and applications (Count I) and the beta-alethine patents and applications (Count II); b) that no new matter in contravention of 35 U.S.C. § 132 was introduced into the

vitaletheine modulator patents and applications by reason of the amendments made by UNM; c) that Knight and Scallen are the only joint inventors of the vitaletheine modulator patents and applications.

Knight and Scallen filed separate timely appeals to the Federal Circuit.

B. Proceedings Before the Federal Circuit

The Federal Circuit in *Regents of University of New Mexico v. Knight* 321 F.3d 1111 (Fed. Cir. 2003) acknowledges that the inventors, Knight and Scallen, are the initial owners of their inventions (App. A10). However, the court failed to determine whether UNM's 1983 Patent Policy is, in fact, a claim of *initial ownership* of employee inventions (with no requirement for inventor assignment) and is, therefore, a violation of the Constitution (Article I, § 8, Clause 8) and the clear precedent of this Court. If so, the 1983 UNM Patent Policy is an invalid contract.

The Federal Circuit sidestepped the question of the lawfulness of the UNM Patent Policy. Instead, it affirmed the district court judgment on breach of contract (refusal to assign the 1992 CIP applications), based upon the "conduct" of the inventors including the 1991 assignments, as showing "intent" on the part of the inventors that UNM "own" the inventions. *See* App. A12-13. The Federal Circuit then affirmed the district court's judgment on ownership based on the affirmance of the breach of contract judgment (App. A13-18).

The Federal Circuit in its determination of ownership ignored established and settled contract law by basing its decision on the "conduct" of the inventors which was, in fact, improperly controlled by the unlawful misrepresentation of *initial* ownership by UNM in its Patent Policy.

The Federal Circuit affirmed the district court's judgment that no new matter had been added to the vitaletheine modulator patents and applications, based upon the faulty conclusion that the changes in structures did not constitute changes in *compounds* (App. A16-17). This conclusion was unduly influenced by the Federal Circuit's failure to enter the science [App. A17, n 7., "We need not enter the scientific dispute whether the amended structures actually describe the vitaletheine inventions correctly."].

The Federal Circuit did not determine the validity/enforceability of the amended vitaletheine modulator patents containing crucial and critical *content* not supported by inventor oaths or declarations in violation of 35 U.S.C. §§ 111 and 115.

The Federal Circuit also failed to apprehend that the inventors' First Amendment rights (academic freedom) were violated by UNM *causing to be published* certain amended patents *under the inventors' names* which UNM knew the inventors believed to be false.

Scallen filed a petition for rehearing *en banc*, and Knight filed a petition for panel rehearing.

The Federal Circuit denied both petitions on April 3, 2003. *See* App. A50-51.

REASONS FOR GRANTING THE PETITION

Overview

The decision below [*Regents of University of New Mexico v. Knight* 321 F.3d 1111 (Fed. Cir. 2003), App. A1-27] squarely conflicts with the Constitution (Article I, § 8, Clause 8) and with the firmly established precedent of this Court concerning the initial ownership of employee inventions. *See U.S. v. Dubilier Condenser Corp.* 289 U.S. 178, 77 L Ed 1114, 53 S Ct. 554, 85 ALR 1488 (1933). It also conflicts with the Federal Circuit's own precedent, *e.g., Beech Aircraft Corp. v. EDO Corp.,* 990 F.2d 1237, 1248, 26 USPQ2d 1572, 1582

(Fed. Cir. 1993), since the UNM 1983 Patent Policy (App. A55-58) clearly claims *initial* ownership of employee inventions without any requirement for assignment by the inventors.

The Federal Circuit in its decision failed to apply established and settled contract principles concerning the *effect* of this crucial misrepresentation of law on the formation and/or enforceability of contracts, *i.e.*, the Patent Policy and the inventor assignments.

If this decision by the Federal Circuit stands, employers would be permitted to deny inventors the initial ownership of their inventions and to use invalid contracts and statements of supposed legal entitlement in order to improperly obtain assignments.

This case also presents a question of substantial public interest, *i.e.*, the loss of patent coverage for the most potent anti-cancer compounds ever described in the scientific literature, the vitaletheine modulators (*Cancer Res.* article., *supra*, page 4). This occurred because UNM, claiming ownership, deleted from the vitaletheine modulator patents and applications coverage for three strikingly effective and potent biological regulators, two of which are anti-cancer compounds. These changes by UNM were made in spite of the strenuous objections of the inventors (Knight and Scallen) and without inventor authorization. UNM substituted two other compounds (taurines), compounds that have no demonstrated anti-cancer activity whatsoever. Then UNM knowingly caused to be published in the inventors' names patents that the inventors know to be wrong (false).

Clearly, this Court's supervisory powers are required to correct this manifest injustice and to protect the public interest.

I. The Federal Circuit Failed to Determine Whether or Not the 1983 UNM Patent Policy is, in Fact, a Claim of Initial Ownership of Employee Inventions With No Requirement to Assign.

The Federal Circuit's failure to recognize that the 1983 UNM Patent Policy is actually a claim of *initial ownership* of employee inventions casts a cloud of uncertainty over the established precedent of this Court concerning initial ownership by inventors. *See Dubilier, supra.*

The 1983 UNM Patent Policy Claims Initial Ownership of Employee Inventions in the Absence of Any Requirement to Assign.

The 1983 UNM Patent Policy (App. A55-58) was declared by the district court to be the applicable and controlling patent policy in this case.

Section 2 of this Policy states:

> "2. All staff members who make inventions or discoveries (i) in the course of research ... . , such inventions and discoveries belong to the University."

That this claim of ownership by UNM is actually a claim of *initial* ownership is made clear in section 5a of that Policy:

> "In the case of any invention or discovery which *initially* belongs to the University under the provisions of section 2 above, ...". [Emphasis added.]

Further confirmation that UNM claims *initial* ownership is found in a subsequent portion of section 5a:

> "If the President decides that the University will not seek to exploit the invention or discovery for the production of income the University shall promptly assign *its* title thereto to the discoverer or inventor, ..." [Emphasis added.]

This quote provides the only mention of the term "assign" in the entire text of the Patent Policy. This Policy clearly claims *initial* ownership by UNM, with not even a suggestion that the inventions ever belonged to the inventors and, therefore, no suggestion that the inventions must be assigned or transferred to UNM. [2]

"Belong" is defined in *Black's Law Dictionary*: "Belong. Vb. 1. To be the property of a person or thing." *Id.* at 148.

Words and Phrases states:

> "Word 'belong' is not a word of conveyance, but a declaration of *existing* title, and does not evidence an intention to convey or transfer title." *Flynn v. Fike*, 291 Ky. 316, 164 S.W.2d 470, 473 (1942). [Emphasis added.]

Id. at 5, 418.

When coupled with the absence of any language concerning assignment or transfer of rights by the inventors and the use of the phrase "initially belongs to" in section 5a, it is clear that "belongs to" in section 2 of the Patent Policy is a claim of *initial* ownership. [3]

The absence of any transfer language in the UNM Patent Policy stands *in contrast* to two recent cases decided by the Federal Circuit. In *University of West Virginia v. Vanvoorhies*, 278 F.3d 1288, 1292 (Fed. Cir. 2002) the University of West Virginia Patent Policy specifically states and requires the "transfer of rights" from the inventors to the University of West Virginia. *Id.* at 1292. In *Chou v. University of Chicago*, 254 F.3d 1347 (Fed. Cir. 2001) a similar *explicit* requirement,

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[2] It is undisputed that neither Knight nor Scallen were hired to invent.

[3] The Federal Circuit states (App. A11) that the Patent Policy requires "signing of patent applications and associated documents ...". These "associated documents" clearly are documents for obtaining patents. Documents transferring ownership *are not necessary* for obtaining patents, so this statement has no relationship to assignment.

i.e., "shall be assigned", is contained in the University of Chicago Patent Statute. *Id.* at 1357.

No such transfer language is contained in the 1983 UNM Patent Policy. *See* App. A55-58.

The claim of *initial* ownership in UNM's 1983 Patent Policy is contrary to the Constitution and the established precedent of this Court.

Article I, § 8, Clause 8 of the Constitution states:

> "The Congress shall have power ... to promote progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries:"

Inventions and patents by law belong to the inventor, unless and until they are assigned to another. *Dubilier, supra* at 187. The UNM Patent Policy claims initial ownership *without even mentioning assignment by the inventor.*

Inventorship provides a *starting point* for determining ownership of patent rights. *Chisum on Patents* (1993) 8, § 22.02, 22-23. [4] In *Beech Aircraft Corp., supra,* the Federal Circuit states:

> "At the heart of any ownership analysis lies the question of who first invented the subject matter at issue, because the patent right *initially* vests in the inventor who may then, barring any restrictions to the contrary, transfer that right to another and so forth." [Emphasis added.]

---

[4] Regarding *inventorship* (Count III), the district court determined that Knight and Scallen are the only joint inventors of the vitaletheine modulator inventions, patents, and applications (Count I). *See* App. A49. It is uncontested that Knight, Mann, and Scallen are the only joint inventors of the beta-alethine inventions, patents, and applications (Count II).

Id. at 1248.

Therefore Knight and Scallen (and Knight, Mann, and Scallen), not UNM, are the *initial owners* of the vitaletheine modulator and beta-alethine inventions, patents and applications, respectively, and are under no contractual obligation to assign.

The claim of *initial* ownership by UNM is contrary to law [Constitution (Article I, § 8, Clause 8); *Dubilier;* and *Beech Aircraft Corp.*]. This *misrepresentation* of law is so fundamental and so flawed as to prevent the formation of a contract concerning ownership between the inventors, Knight and Scallen, and UNM.

A misrepresentation can prevent *formation* of a contract. *Restatement Contracts 2d* (1981), 1, § 163, 443. This result, *i.e.*, that a contract concerning ownership (the 1983 Patent Policy) was never formed between UNM and Knight and Scallen, follows "if the misrepresentation relates to the very *nature* of the proposed contract itself and not merely to one of its nonessential terms". *Id.* at 443.

UNM's claim of *initial* ownership is the very *essence and foundation* of the entire Patent Policy. This *misrepresentation* of law either prevented formation of a contract between UNM and the inventors or, in the alternative, rendered it void and unenforceable.

The rules that determine the consequences of a misrepresentation of such a matter of law are the same as those that determine the consequences of a similar misrepresentation of any other fact. *Restatement Contracts 2d* 1, § 170, 463.

The assertions of ownership in the Co-Inventor agreements (App. A11-12) and the assertions of "legal entitlement" contained in the assignments (*e.g.*, App. A59) are based upon this same crucial and fundamental *misrepresentation* of law.

II. The Federal Circuit Failed to Test the Validity of the 1991 Assignments Using Established Principles of Contract Law.

The 1991 Assignments Are Invalid Due to UNM's Misrepresentation of Initial Ownership in the Patent Policy and UNM's Misrepresentation of Legal Entitlement in the Assignments Themselves.

Rather than analyzing the UNM Patent Policy's unlawful claim of initial ownership, the Federal Circuit based its decision regarding breach of contract [5] and ownership *entirely* on the *conduct* of the inventors in submitting to UNM's demands for assignment, without recognizing the effect of the crucial misrepresentation of law in the Patent Policy on the inventors' submission. *See* App. A12-13. This conduct includes the filing of an invention disclosure in 1986, the assigning of the 1990 parent patent applications in 1991, and the signing by the inventors of the Co-Inventor agreements in 1991. The Federal Circuit states that the "conduct" of the inventors, Knight and Scallen, indicates an "intent" that UNM own their inventions. *See* App. A12-13.

Prior to the present litigation Knight and Scallen as scientists, not lawyers, were certainly not experts in patent law and were unable to judge the legitimacy of UNM's claim of *initial* ownership. In 1986 when the inventions were reduced to practice and in 1991 when the assignments of the 1990 applications were demanded, Knight and Scallen were in a *relationship of trust* with UNM, and it was reasonable for the inventors to rely on UMM as the expert.

The *Restatement Contracts 2d*, 1, § 169 states:

> "... , the recipient is not justified in relying on it [assertion] *unless* the recipient (a) stands in such a relation of trust and confidence to the person whose

---

[5] The "breach of contract" refers to the refusal of Knight and Scallen to assign the five 1992 CIP applications when they were asked to do so in 1996.

> opinion is asserted that the recipient is reasonable in relying on it or (b) reasonably believes that, as compared with himself, the person whose opinion is asserted has special skill, judgment or objectivity with respect to the subject matter,";

Id. at 459.

Further, § 170 of the *Restatement* states:

> " ... , if the maker of the representation purports to have special expertise in the law which the recipient does not have, reliance on the opinion may be justified (§ 167(b)). If the lawyer states his opinion of law to a layman, the layman is entitled to assume his professional honesty and may justifiably rely on his opinion ...".

Id. at 463.

Knight and Scallen's conduct did *not* reflect an *intent* by the inventors that UNM be the owner of their inventions, but rather reflected their belief *at that time* that they had no choice in the matter and that their "refusal" would be unlawful. Scallen contends that this "conduct" was *improperly controlled/influenced* by the *misrepresentation of law* included in the Patent Policy, i.e., UNM's illicit and unlawful claim of *initial* ownership, and the repeated insistence by UNM officials that assignment was legally required.

A misrepresentation is an assertion that is not in accord with the facts. *Restatement Contracts 2d*, 1, § 159, 426. *Restatement Contracts 2d*, 1, Topic 1, "Misrepresentation" at 425 states:

> " In order to void a contract four things must be shown. *First*, there must have been a misrepresentation (§ 159). *Second*, the misrepresentation must have been either fraudulent or material (§ 162). *Third*, the misrepresentation must have induced the recipient to make the contract (§

167). *Fourth,* the recipient's reliance on the misrepresentation must have been justified." [Emphasis added.]

In addition see *Id.* §§ 169 and 170.

Clearly, all four of these requirements are met in this case.

The assignments (*e.g.,* App. A59-60) begin with the assertion:

> "whereas under its *stated policy* [Patent Policy] Assignee [UNM] is *legally entitled to* ... the entire right, title , and interest ..." [Emphasis added.]

The Co-inventor agreements repeat the same false assertion contained in the Patent Policy, *i.e.,* that UNM is the owner.

This misrepresentation was an *improper inducing cause* for Knight and Scallen to enter into the 1991 assignments and Co-Inventor agreements. As *The Restatement Contracts* 2d, 1, §167 states:

> "A misrepresentation is not a cause of a party's making a contract *unless he relied on the misrepresentation in manifesting his assent.* [Emphasis added.]

Id. at 453.

Therefore the five 1991 assignments are invalid or, in the alternative, void/unenforceable, since UNM claimed in these assignments that it was "*legally entitled*" to them when, *in fact and in law,* it was *not* legally entitled to an assignment since there is no contractual basis for assignment in the Patent Policy. *See* App. A55-58.

III. UNM Amended Certain Vitaletheine Modulator Patents and Applications, Changing the Essential Nature of the Anti-Cancer Compounds Invented by Knight and Scallen, Without Inventor Authorization and Over the Strenuous Objections of the Inventors.

A. The Experimental Scientific Data Prove that the Amendments Added New Matter.

The Federal Circuit misapprehended the *nature* of the amendments to the vitaletheine modulator patents and applications (App. A15-17). The court's statement ("We need not enter the scientific dispute over whether the amended structures actually describe the vitaletheine inventions correctly.") further contributes to this misapprehension. *See* App. A17, n 7. It is true that the Knight and Scallen structures were *changed* by UNM, but it is also true that the *underlying compounds*, described by the *amended* structures, are *fundamentally different* from the *compounds* synthesized by Knight and Scallen and used in all of the inventors' enabling experiments, as reported in *Cancer Research*, as reported in the inventor authorized three 1992 CIP applications, and in U.S. 5,370,868 which was not amended in any way and issued directly from one of the CIPs (07/928,725) in 1994.

The present case is *not* a question of "correction" as assumed by the Federal Circuit in its opinion. *See* App. A16-17. The compound structures, substituted by means of amendments *into* the Knight and Scallen vitaletheine modulator patents and applications by UNM (beta-alanyl-taurine for vitaletheine V_4 and carbobenzoxy-beta-alanyl-taurine for the Knight and Scallen sulfenate-linked benzyl carbamate dimer) are structures of compounds made by the

licensee's agent Murray [6], which are clearly *different compounds* from the Knight and Scallen *compounds*, based upon differing chemical, physical, and biological properties and characteristics. [7]

In other words, the two different sets of structures describe two fundamentally different sets of compounds.

The amendments also deleted from the claims a third compound, vitalethine, included by the inventors in the 1992 CIP applications and taught in the '868 patent. Vitalethine treatment of a very aggressive melanoma in mice was extremely successful: 8 of 10 mice survived when treated with vitalethine (30 fg/kg, administered by injection in saline once every two weeks); 0 of 10 mice survived when treated with saline only. See *Cancer Research* article, *supra*, Table 1, page 5629. *See* App. A87.

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[6] It may seem that the substitution of the compounds synthesized by Murray (taurines) for the Knight and Scallen vitaletheine modulator compounds is inexplicable. It should be noted that Murray and the licensee (Taub) are listed as inventors on patent applications, filed in 1995 three years *after* the filing of the Knight and Scallen 1992 CIP applications. These Murray and Taub applications appear to include *the original Knight and Scallen vitaletheine modulator compounds*, the very compounds *deleted* from the Knight and Scallen patents by UNM and its agents (attorneys paid by Taub). For example, *see* U.S. 6,007,819, Taub, F., Perun, T.J., Murray, C.K., Daughenbaugh, R.J., and Lednicer, D., "Methods of Inducing Immunity Using Low Molecular Weight Immune Stimulants", issued December 28, 1999.

[7] The Federal Circuit states (App. A16): "As the district court found ... Murray and Wallace synthesized the vitaletheine compounds according to Scallen and Knight's descriptions." No documentary evidence, *e.g.*, laboratory notebooks, was presented either in discovery or at trial substantiating this assertion. In fact the record, based upon declarations by Murray and Wallace to the Patent Office, clearly demonstrates that both Murray and Wallace significantly changed the Knight and Scallen procedures taught in U.S. 5,370,868.

The 30 fg/kg dose of vitalethine is 0.000000000000030 grams! This compound and the sulfenate-linked benzyl carbamate dimer of vitaletheine are by far the most potent anti-cancer compounds ever described in the scientific literature.

Comparing the Knight and Scallen vitaletheine modulator compounds with the substituted compounds (taurines), the infrared (IR) spectra are *different*, the mass spectra are *different*, and the elemental analyses are *different*. These are *objective* scientific experimental *measurements* of the compounds themselves, which do not depend upon the structures proposed by the scientists.

For example, the mass spectral data (presented at trial) show that four significant mass ions (above 200 mass units) were observed for the Knight and Scallen sulfenate-linked benzyl carbamate dimer of vitaletheine, i.e., 726 (molecular ion), 547, 378, and 356. Eight mass ions were observed for carbobenzoxy-beta-alanyl-taurine, the compound substituted by UNM, *i.e.*, 755, 474, 396, 394, 392, 331, 225, and 214. *Note that there is not one single ion of the same mass in both spectra.*

Therefore, these are obviously different compounds.

Mass spectrometers and infrared spectrometers are objective and unbiased. Just as different people have different fingerprints, different chemical compounds have different molecular fingerprints.

The failure of UNM to offer experimental evidence that the substituted taurine compounds had/have *any* significant anti-cancer efficacy whatsoever is telling. This is crucial because of the *extraordinary* anti-cancer and immune enhancing activities of the original Knight and Scallen vitaletheine modulator *compounds* (as shown in U.S. 5,370,868 and the *Cancer Research* article, *supra*).

Therefore, the amendments *did* introduce new matter (*new compounds*) and *corrupted the scientific integrity* of Knight and Scallen's inventions. Therefore, UNM added new matter in violation of 35 U.S.C. § 132.

If these amendments present in the '313, '536, and '025 patents are allowed to stand, patent *compound* coverage for the Knight and Scallen enabling vitaletheine modulator compounds (those in U.S. 5,370,868) will be lost. Compound coverage is critical for commercial development. As noted above, the vitaletheine modulators are the most potent anti-cancer compounds ever described in the scientific literature.

This result, *i.e.*, the loss of patent compound coverage and therefore commercial development of the Knight and Scallen vitaletheine modulators, would be *emphatically* against the *public interest*, particularly the interest of the untold numbers of citizens who suffer or will suffer from cancer and numerous immune related diseases, *e.g.*, AIDS, autoimmune disease, and other immunological deficiency states.

A suit to enforce patents and related contracts involves the public interest, as well as the interest of the adverse parties. In *Precision Co., v. Automotive Co.*, 324 U.S. 806, 65 S. Ct. 993, 89 L. Ed. 1381 (1945) this Court states: "A patent by its very nature is affected with a public interest." *Id.* at 816.

Clearly, this Court's supervisory powers are required to correct this manifest injustice and to protect the public interest.

B. Since August of 1994 UNM Has Conducted Patent Prosecution Unlawfully.

Since August of 1994 UNM has not permitted Knight and Scallen to participate in patent prosecution. UNM and its agents have conducted patent prosecution of the Knight and Scallen (and Knight, Mann, and Scallen) patents and applications: 1) without power of attorney from the

inventors, 2) without prior review of patent applications by Knight and Scallen, and 3) without valid declarations or supplemental declarations from the inventors. See "Facts", pages 4-7. *See* Scallen's *First Declaration*, ¶¶ 7-15 (App. A63-64). Thus, UNM has violated 35 U.S.C. § 111 which requires inventor authorization, 35 U.S.C. § 115 which requires valid inventor declarations for issuing patents, and 37 C.F.R. §§ 1.63 and 1.67(c) which require either a new declaration or a supplemental declaration for any changes in the patent application, whether these changes are to specifications or to claims.

The Federal Circuit's statement (App. A13) that the inventors "refused to cooperate" with UNM in patent prosecution is unsupported by the record. The only refusal on the part of the inventors was their refusal in 1996 to assign the 1992 CIP applications and their progeny. In fact the inventors were prevented from cooperating by UNM from August of 1994 on, long before there was any dispute concerning the nature of the compounds. UNM is still preventing cooperation by the inventors to this very day.

The Federal Circuit has failed to apprehend the *manner* by which UNM and its agents deceived the Patent Office into accepting "correction of structures", without revealing to the Patent Office that the amendments actually changed the *compounds*. UNM and its agents falsely represented to the examiner that the inventors agreed with the amendments. This representation was crucial, material, clearly *false*, and UNM knew it. *See* App. A80-86.

Patent, to be valid, had to be granted on application, *supported by oath*, of original and first inventor. *Kennedy v. Hazelton* 128 U.S. 667, 672, 32 L Ed 576, 9 S Ct 202 (1888). This Court states:

> "The patent law makes it essential to the validity of a patent, that it shall be granted on the application, supported by the oath, of the original and first

> inventor, ... whether the patent is issued to him or to his assignee. A patent which is not supported by the oath of the inventor, but applied for by one who is not the inventor, is unauthorized by law, and void, and, whether taken out in the name of the applicant or of any assignee of his, confers no rights as against the public."

Id. at 672.

In *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1052 (Fed. Cir. 1995) the court states:

> "... the information disclosed in the inventor's patent application must be *that which is actually known to him*. The statute requires that he submit an oath to this effect. See 35 U.S.C. § 115 (1988)." [Emphasis added.]

Id. at 1052.

Further, the *Glaxo* court states;

> "The court finds comfort in the regulations requiring that the inventor sign an oath attesting that he has reviewed the application, 37 C.F.R. §§ 1.41(a), 1.51(a)(2) & § 1.63(b)(1), (2), reasoning that Glaxo must have at least let Crookes [the inventor] review the application before it was filed."

Id. at 1054, note.

The substituted compounds (taurines), introduced by UNM in the amendments, were/are not "known" in the sense that they were not synthesized or used by the inventors, Knight and Scallen in any way. UNM patent administrator Quintana admitted at trial that the inventor declarations included in the *amended* patents and applications by UNM were the *very same* declarations *signed at the time of the CIP applications in 1992* in which the inventors swore (in 1992) to the accuracy of the *compounds*

referred to in the specifications and the claims *of the 1992 CIP applications, prior* to the entry of any of the amendments (1995-1996). Compare the inventor declarations used to support the inventor approved and authorized U.S. 5,370,868 (App. A68-72) with the very same inventor declarations used by UNM to support the *amended* patent, *e.g.*, 5,578,313 (App. A75-79). *See* Scallen's *First Declaration*, ¶¶ 7-15 (App. 63-64).

The inventors never did and never could swear to the accuracy of any of the *amended patents*; the '313 patent issued, November 26, 1996; the '536 patent, August 1, 2000; and the '025 patent, November 27, 2001. The inventors knew, and still know, that the compounds claimed in these *amended* patents are simply wrong. *See* App. A80-86.

Therefore the '313, '536, and '025 patents, and any other patents similarly amended, do not satisfy the requirements of *Kennedy v. Hazelton* and *Glaxo, supra*, violate 35 U.S.C. §§ 111 and 115, and are invalid.

IV. The Consequent Publication by UNM of Patents in Knight and Scallen's Names, Containing Unauthorized Fundamental Changes Which the Inventors Know to be Wrong, Violates Knight and Scallen's Free Speech (Academic Freedom) Under the First Amendment.

The 1940 Statement of Principles on Academic Freedom and Tenure, developed by the American Association of University Professors (AAUP) and the Association of American Colleges and Universities, is the fundamental statement on academic freedom for faculty in higher education. [8] *The 1940 Statement* includes this definition of academic freedom:

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[8] *The 1940 Statement* is included in the UNM *Faculty Handbook*. A New Mexico case [*Garcia v. Middle Rio Grande Conservancy Dist.*, 121 N.M. 528, 918 P.2d 7 (1996)] held that a written personnel policy was a "written contract" and the UNM *Faculty Handbook* is incorporated into Scallen's employment contract (section 8). *See* App. A54. Therefore, in the present

> "Teachers are entitled to full freedom in research and in the *publication* of the results, ..." [Emphasis added.]

This Court has relied on *The 1940 Statement*'s definition of academic freedom. [9] See *Roemer v. Maryland Public Works Bd.*, 426 U.S. 736, 756 (1976); *Tilton v. Richardson*, 403 U.S. 672, 681-82 (1971).

Although this Court has consistently recognized that academic freedom is a First Amendment right, the *scope* of that First Amendment right for university faculty remains unclear. The present case requires determination by this Court to further define that scope.

The amended patents and applications are a violation of Knight and Scallen's First Amendment rights. In *University of California Regents v. Bakke*, 438 U.S. 265, 312 (1978), Justice Powell states:

> "Academic freedom, though not a specifically enumerated constitutional right, long has been viewed as a special concern of the First Amendment."

In *Edwards v. Aguillard*, 482 U.S. 578, 586, 107 S. Ct. 2573 (1987) this Court (quoting the Fifth Circuit Court of Appeals) states:

> "academic freedom embodies the principle that individual instructors are at liberty to teach that which they deem to be appropriate in the exercise of their professional judgment". 765 F.2d at 1257.

Id. at 586, n 6.

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instance, a contract exists between UNM and its faculty members concerning *The 1940 Statement of Principles on Academic Freedom and Tenure.*

[9] *See* Donna R. Euben, "Academic Freedom of Individual Professors and Higher Education Institutions: The Current Legal Landscape" (May, 2002) http://www.aaup.org/Com-a/aeuben.HTM

A patent is a *teaching* and a *publication*, reporting the results and utilities of Knight and Scallen's *research*.

UNM has knowingly caused to be published under Knight and Scallen's names and over Knight and Scallen's protests (*e.g.*, App. A80-86) scientific assertions and content which Knight and Scallen never asserted, nor approved, and which they know to be false. UNM thus corrupted the scientific integrity of these Knight and Scallen *publications* (patents).

Therefore, Knight and Scallen's First Amendment rights have been violated by UNM.

CONCLUSION

For the foregoing reasons, Petitioners respectfully request that their petition for writ of certiorari be granted.

Respectfully submitted,

Terence J. Scallen, M.D., Ph.D.,
Petitioner, Pro Se
PO. Box 651
Borrego Springs, CA 92004-0651
Telephone: 760-767-3444

Galen D. Knight, Ph.D.
Petitioner, Pro Se
3205 Arizona NE
Albuquerque, NM 87110

Supreme Court, U.S.
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NO. _____

IN THE
SUPREME COURT OF THE UNITED STATES

TERENCE J. SCALLEN., *Petitioner*
AND,
GALEN D. KNIGHT, *Petitioner*
vs.
THE REGENTS OF THE UNIVERSITY
OF NEW MEXICO, *Respondent.*

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

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APPENDIX FOR WRIT OF CERTIORARI

Terence J. Scallen, M.D., Ph.D., *Pro Se*
PO. Box 651
Borrego Springs, CA 92004-0651
Telephone: 760-767-3444

and

Galen D. Knight, Ph.D., *Pro Se*
3205 Arizona NE
Albuquerque, NM 87110

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[*Regents of University of New Mexico v. Knight*, 321 F.3d 1111 (Fed. Cir. 2003)]

The REGENTS OF THE UNIVERSITY OF NEW MEXICO, Plaintiff-Appellee,

v.

Galen D. KNIGHT. Defendant-Appellant,

and

Terence J. Scallen, Defendant-Appellant.

Nos. 02-1018, 02-1019

United States Court of Appeals,

Federal Circuit.

Feb. 28, 2003.

Paul Adams, Peacock, Myers & Adams, P.C., of Albuquerque, NM, for plaintiff-appellee. With him on the brief was Stephen A. Slusher.

Galen D. Knight, Ph.D., of Albuquerque, NM, pro se.

Terence J. Scallen, M.D., Ph.D., of Borrego Springs, CA, pro se.

Before NEWMAN, LOURIE, and SCHALL, Circuit Judges.

LOURIE, Circuit Judge.

Galen D. Knight and Terence J. Scallen separately appeal from the decisions and orders of the United States District Court for the District of New Mexico: granting the Regents of the University of New Mexico ("UNM") summary judgment that UNM is the owner of seven patents and patent applications relating to beta-alethine compounds.

Regents of the Univ. of N.M. v. Knight, No. CIV 99-577, slip op. at 2 (D.N.M.) Aug. 9, 2000) ("*Count II Summary Judgment*"); declaring UNM to be the owner of eleven patents and patent applications relating to vitaletheine compounds, *Regents of the Univ. of N.M. v. Knight*, No. CIV 99-577, slip op. at 2-3 (D.N.M. Jan. 29, 2001) ("*Count IV Summary Judgment*"); dismissing Scallen and Knight's counterclaims as barred by the Eleventh Amendment, *Regents of the Univ. of N.M. v. Knight*, No. CIV 99-577, slip op. at 5 (D.N.M. Feb. 27, 2001) ("*Dismissal of Counterclaims*"); appointing a special master, *Regents of the Univ. of N.M. v. Knight*, No. CIV 99-577, slip op. at 1 (D.N.M. Mar. 21, 2000 ("*Special Master*"); and awarding costs and the special master's fee to UNM, *Final Order* at 5. We affirm-in-part, reverse-in-part, vacate-in-part, and remand.

BACKGROUND

Dr. Scallen was a professor of biochemistry and medicine at UNM. Dr. Knight was hired as a faculty staff member in Scallen's laboratory. From 1983 to 1985, Scallen, Knight, and Dr. Paul Mann engaged in cancer research that led to inventions relating to beta-alethine and vitaletheine. UNM filed five patent applications based on these inventions on July 6, 1990. Two of these applications were directed to methods for using beta-alethine compounds to treat cancer; [1] three were directed to vitaletheine modulators and methods for their use.[2] The inventors executed

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[1] U.S. Patent Application 07/549,103 (Knight, Mann, & Scallen, "Beta - Alethine as Anti-Tumor Agent"); U.S. Patent Application 07/549,104 (Knight, Mann, & Scallen, "Beta-Alethine Use in Cell Culture and Therapy").

[2] U.S. Patent Application 07/549,105 (Knight & Scallen), "Vitaletheine Modulators in the Prophylaxis and Treatment of Disease"); U.S. Patent Application 07/549,438 (Knight & Scallen, "Vitaletheine Modulators and Use in Cell Cultures"); U.S. Patent Application 07/549,438 (Knight & Scallen), "Vitaletheine Modulators and Use in Cell Cultures"); U.S. Patent

declarations, power of attorney, and small business entity verifications for each of the applications. In 1991, Scallen, Knight, and Mann assigned the two beta-alethine applications to UNM, and Scallen and Knight assigned the three vitaletheine applications to UNM. On April 4, 1991, Scallen and Knight signed a UNM Co-Inventor Agreement relating to the vitalethine inventions. [3]

In 1992, UNM filed five continuation-in-part ("CIP") applications, [4] one from each of the 1990 parent applications. The inventors again executed declarations, power of attorney, and small business entity verifications for the CIP applications. Mann eventually assigned the two beta-alethine CIP applications to UNM; Scallen and Knight never assigned any of the CIP applications to UNM.

In February 1994 the funding for Scallen's laboratory was lost and Knight's employment was terminated. Approximately six months later, UNM entered into an agreement with Dovetail Technologies, Inc., whereby UNM

Application 07/549,440 (Knight & Scallen, "Therapeutic Use of Vitaletheine Modulators in Neoplasia").

[3] UNM claims that a Co-Inventor Agreement relating to the beta-alethine inventions was also executed between the inventors and UNM. That agreement has not been "found" and is not included in the record. In his declaration, however, Scallen acknowledges that in 1991 the inventors signed two Co-Inventor Agreements, one for the inventions in the three vitaletheine parent applications and one for the inventions in the two beta-alethine parent applications.

[4] U.S. Patent Application 07/924,977 (Knight, Mann, & Scallen, "Beta-Alethine as Anti-Tumor Agent"); U.S. Patent Application 07/919,253 (Knight, Mann, & Scallen, "Beta-Alethine Use in Cell Culture and Therapy"); U.S. Patent Application 07/910,892 (Knight & Scallen, "Vitaletheine Modulators in the Prophylaxis and Treatment of Disease"); U.S. Patent Application 07/941,926 (Knight & Scallen, "Vitaletheine Modulators and Use in Cell Cultures"); U.S. Patent Application 07/928,725 (Knight & Scallen, "Therapeutic Use of Vitaletheine Modulators in Neoplasia").

granted a worldwide exclusive license to Dovetail for the beta-alethine and vitaletheine inventions and warranted that UNM is the owner of the related patents and applications. Dovetail then contracted with a company referred to as Hauser to synthesize the compounds relating to the vitaletheine inventions. Dr. Christopher Murray, Hauser's Director of Chemical Processing Services, determined that the vitaletheine compounds could not be synthesized as described by Scallen and Knight and concluded that two chemical structures in the vitaletheine applications were incorrect. UNM then retained Dr. Shield Wallace of Professional Analysis, Inc. to synthesize and characterize the compounds disclosed in the vitaletheine applications. He, too, concluded that two of the structures in the applications were incorrect. Murray and Wallace determined what they considered to be the correct structures of the compounds, and UNM submitted to the U.S. Patent and Trademark Office ("PTO") amendments changing Scallen and Knight's "vitaletheine V_4" and "benzyl derivative of vitaletheine" structures in the vitaletheine applications to the structures for beta-alanyl-taurine and carbobenzoxy-beta-alanyl-taurine, respectively. Scallen and Knight objected to those amendments, both to UNM and to the PTO, but they were accepted by the PTO as not being directed to new matter.

Scallen retired in September 1995 and worked part-time through June 1996. In 1999, Dovetail notified UNM that it was in breach of the warranty of ownership provision of their license agreement. UNM considered that alleged breach to be based on Scallen and Knight's refusal to assign to UNM their rights in the CIP applications. On May 21, 1999, UNM accordingly filed suit against Scallen and Knight, seeking declaratory, injunctive, and monetary relief on various patent and state law claims. Count I of UNM's complaint sought a declaration of ownership of the vitaletheine patents and applications. Count II sought a declaration of ownership of the beta-alethine patents and applications. Count III sought a declaration and, if

necessary, correction of inventorship of U.S. Patents 5,370,868 and 5,578,313, both directed to methods for using vitaletheine modulators. Count IV alleged breaches of the UNM Intellectual Property Policy and the Co-Inventor Agreement. Count V alleged intentional interference with the Dovetail license agreement. Count VI alleged conversion or, in the alternative, replevin. Count VII alleged slander of title.

Scallen and Knight, acting *pro se*, each filed counterclaims against UNM. Scallen sought money damages for UNM's breach of its duties of care, good faith, and fair dealing. Scallen also sought a declaration determining his rights in the beta-alethine and vitaletheine inventions and patents. Knight filed counterclaims for various contract and tort actions, including breach of contract, intentional interference with prospective economic advantage, abuse of process, slander, and breach of fiduciary duty. Knight sought a declaration of ownership of the beta-alethine and vitaletheine patents and applications as well as monetary relief for withheld royalties and lost wages.

Because of the "technical nature" of the case, the district court *sua sponte* appointed as special master Ray Regan, a patent attorney, to evaluate all pending and future motions. *Special Master* at 1. The court instructed UNM to pay Regan's compensation initially, but indicated that the losing party would ultimately be responsible for Regan's compensation. *Id.*

On May 31, 2000, the special master issued his first report, which included findings of fact, conclusions of law, and recommendations pertaining to ownership of the beta-alethine patents and applications (*i.e.*, Count II). *Regents of the Univ. of N.M. v. Knight*, No. CIV 99-0577 (D.N.M. May 31, 2000) ("First Special Master's Report"). The special master found, *inter alia*, that Scallen and Knight had assigned the beta-alethine patent applications to UNM and that they had refused to sign subsequent assignments because they

disagreed with UNM's prosecution of the vitaletheine applications. *Id.* at 20-21. Based on a review of the 1991 Joint Assignments, the 1983 UNM Patent Policy, the powers of attorney, and the inventors' declarations claiming small entity status, the special master concluded that there were no genuine issues of material fact and that Scallen and Knight were obligated to assign the beta-alethine patents and applications to UNM. *Id.* at 20-23. Upon conducting a *de novo* review of the special master's report, the court adopted the special master's recommendations in their entirety and granted summary judgment to UNM on Count II. *Count II Summary Judgment* at 2-3. The court directed Scallen and Knight to execute an assignment of the beta-alethine patents and applications to UNM. *Id.* at 2.

On September 20, 2000, the special master issued a second report, which addressed the breach of contract claim (*i.e.*, Count IV). *Regents of the Univ. of N.M. v. Knight*, No. CIV 99-0577 (D.N.M. September 20, 2000) ("Second Special Master Report"). The special master found that neither defendant had shown the existence of a genuine issue of material fact and that Scallen and Knight had breached their agreements with UNM by not executing assignments of the beta-alethine patents and applications. *Id.* at 28. Again, the court adopted the report in its entirety and entered summary judgment in favor of UNM on Count IV. *Count IV Summary Judgment* at 2-3.

The court then granted UNM's motion to amend its complaint, allowing UNM to withdraw any request for money damages. *Dismissal of Counterclaims* at 2-3. The court observed that UNM, as an arm of the state, was entitled to Eleventh Amendment immunity, but noted that by filing suit UNM had waived its immunity from claims in recoupment arising out of the same transaction or occurrence as its claims. Id. at 3. Because UNM's amended complaint now sought only declaratory and injunctive relief, the court found that Scallen and Knight's counterclaims for

money damages were no longer claims in recoupment. *Id.* at 4. The court therefore dismissed Scallen and Knight's counterclaims as barred by the Eleventh Amendment. *Id.* The court later granted UNM's motion to dismiss Counts V, VI, and VII. *Regents of the Univ. of N.M. v. Knight*, No. CIV 99-577 (D.N.M. June 19, 2001).

After a bench trial limited to issues dealing with the vitaletheine patents and applications, the court issued its findings of fact and conclusions of law. *Regents of the Univ. of N.M. v. Knight*, No. CIV 99-577 (D.N.M. Sept. 10, 2001). First, the court found that the organic compounds described in the parent and CIP applications inherently had the structures of the amendments. *Id.* at 13. Relying on a presumption that the PTO had correctly determined that the amendments did not introduce new matter, the court concluded that the amendments did not violate 35 U.S.C. § 132. *Id.* at 14. Secondly, the court found that Scallen and Knight had failed to prove by clear and convincing evidence that U.S. Patent 6,096,536 and the '313 patent are invalid. *Id.* at 15. Third, the court concluded that UNM is the owner of the vitaletheine patents and applications (*i.e.*, Count I), and fourth, the court concluded that Scallen and Knight are the only, joint and properly named inventors of the vitaletheine patents and applications (*i.e.*, Count III). *Id.*

On September 10, 2001, the court issued its final order. In that order the court declared UNM to be the owner of the beta-alethine and vitaletheine patents and applications. *Final Order* at 1-4; declared that no new matter had been added to the vitaletheine applications by amendment to the claimed structures, *id.* at 4; declared that Scallen and Knight are the only and joint inventors of the vitaletheine patents and applications, *id.* at 5; and ordered Scallen and Knight to reimburse UNM for the special master's fees and to pay UNM's costs, *id.*

Scallen and Knight timely appealed; and Counts I–IV are before us. We have chosen to address Scallen and Knight's appeals with respect to both the merits and the award of costs and fees in this one opinion. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review a district court's grant of summary judgment *de novo*, reapplying the same standard used by the district court. *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315, 47 USPQ2d 1272, 1275 (Fed.Cir.1998). Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ. P. 56(c). "The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

In deciding issues not unique to our exclusive jurisdiction, we apply the law of the regional circuit in which the district court sits—here the Tenth Circuit. *See Midwest Indus., v. Karavan Trailers Inc.*, 175 F.3d 1356, 1359, 50 USPQ2d 1672, 1675 (Fed.Cir.1999) (en banc in relevant part). We review the district court's decisions on state law—here, that of New Mexico. *See Univ. of W. Va. v. Vanvoorhies*, 278 F.3d 1288, 1296, 61 USPQ2d 1449, 1453 (Fed.Cir.2002).

A. *Breach of Contract*

On appeal, Scallen and Knight argue that the district court erred in concluding that they had breached their contracts with UNM. They assert that UNM's misrepresentation of its ownership of the beta-alethine and vitaletheine inventions prevented the formation of a valid contract. Specifically, Scallen and Knight contend that UNM's claim of *initial* ownership of the inventions is

contrary to the U.S. Constitution, 35 U.S.C. § 261, and case law holding that inventions and patents belong to the inventor unless and until they are assigned to another. Scallen also argues that, even if valid, neither the UNM Patent Policy nor his employment contract mentions assignment by the inventor. Thus, Scallen and Knight assert that they have no contractual obligation to assign their inventions to UNM.

UNM responds that Scallen and Knight are contractually obligated to assign the beta-alethine and vitaletheine patents and applications to UNM. UNM asserts that that obligation arises from employment contracts, the UNM Patent Policy, and co-inventor agreements, which acknowledge UNM's ownership of the inventions. UNM argues that Patent Policy's statement that "such inventions and discoveries *belong to* the University" obligates the inventors to transfer ownership of the inventions to UNM, even without use of the word "assign." UNM further argues that Scallen and Knight's conduct, including their submission of invention disclosures, their 1991 assignments of the parent applications, and their compliance with the terms of the Patent Policy, confirms the existence of an obligation to assign.

State law governs contractual obligations and transfers of property rights, including those relating to patents. *See Jim Arnold Corp. v. Hydrotech Sys. Inc.*, 109 F.3d 1567, 1572, 42 USPQ2d 1119, 1123 (Fed.Cir.1997). Accordingly, we apply New Mexico state law to UNM's breach of contract claim.

Both Scallen and Knight are bound by the UNM Patent Policy. Each year Scallen and UNM entered into a written faculty contract which at the times relevant here, incorporated the 1983 UNM Patent Policy contained in the Faculty Handbook.[5] The Patent Policy's terms and

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[5] Upon a motion by Scallen, the district court issued an order declaring the 1983 Patent Policy to be the controlling patent policy in the lawsuit,

conditions broadly apply to all "staff members", which includes "any faculty member, student, or any other person associated with the teaching or research staffs of the University." That certainly includes Scallen, who was a faculty member. Although Knight, as a faculty staff member, had no employment contract with UNM, he too was bound by the Patent Policy. Under New Mexico law, a written personnel policy may form an implied employment contract. *E.g., Garcia v. Middle Rio Grande Conservancy Dist.*, 121 N.M. 728, 918 P.2d 7, 10-11 (N.M.1996); *Forrester v. Parker*, 93 N.M. 781, 606 P.2d 191, 192 (N.M.1980). The 1983 UNM Patent Policy thus created an implied contract between Knight and UNM that governed the relationship between Knight and UNM. Thus, we agree with the district court's conclusion that both Scallen and Knight were bound by the Patent Policy.

Scallen contests the Patent Policy's validity on the ground that UNM misrepresented its initial ownership of the inventions. His point is that 35 U.S.C. § 261 vests ownership of a patent in an inventor and the Patent Policy cannot override the statute. While Scallen is correct that initial ownership of a patent vests in the inventor by operation of law, *Beech Aircraft Corp. v. EDO Corp.*, 990 F.2d 1237, 1248, 26 USPQ2d 1572, 1582 (Fed.Cir.1993), § 261 provides that inventors can assign all or part of their interest in a patent. Scallen and Knight did so in the Joint Assignments and agreed to do so in the Co-Inventor Agreement. The Co-Inventor Agreement, signed by Scallen and Knight on April 4, 1991, refers to the inventions described in the three vitaletheine parent applications. The parties also acknowledge a similar Co-Inventor Agreement was executed for the Inventions described in the two beta-alethine parent applications. In addition, Scallen and Knight

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Regents of the Univ. of N.M. v. Knight, No. CIV 99-0577, slip op. at 4 (D.N.M. March 21, 2000). We will also treat the 1983 Patent Policy as the controlling policy.

executed five Joint Assignments in 1991, assigning the five parent applications to UNM.

Having held that Scallen and Knight were bound by the applicable contracts, we turn now to the contents of those agreements. The Patent Policy provides:

> All staff members who make inventions or discoveries (i) in the course of research carried out under their direction and having all or any part of the cost paid from University funds ..., or (ii) which are the direct result of their duties with the University, or (iii) which are made, in whole or in part, using University resources or facilities, shall disclose to the President all such inventions and discoveries.... [S]*uch inventions and discoveries belong to the University.*
>
> ... Each staff member who makes an invention or discovery covered by parts (i), (ii), or (iii) ... has a duty to cooperate fully with the University, or such other party as may be designated by the University ... in all reasonable and lawful acts required to permit full exploitation of the invention or discovery. Such cooperation shall include ... providing information needed for preparation of patent applications and associated documents [and] review and *signing of patent applications and associated documents* ....

(emphases added). Similarly, the Co-Inventor agreement states that "the University is the owner of the Inventions." [6] It continues: "The Inventors [and the University] shall cooperate with each other in the timely and responsive preparation and review of material relating to the Invention, to the prosecution of patent applications and the obtaining of patents thereon, and to the development or exploitation of the Invention," and according to the five Joint Assignments,

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[6] The Agreement further provides that "[I]t is understood by the Parties that UNM as the owner of the Inventions has the right to assign or license any of the Inventions."

Scallen and Knight did "sell, assign, and transfer unto [UNM} all right, title, and interest" in the inventions, in any patents that may issue from those inventions, and "in and to any and all divisions, reissues, continuations, and extensions thereof." The Joint Assignments further require Scallen and Knight "to sign all lawful papers, to execute all divisions, continuations, substitutions, renewal, and reissue applications, [and] to execute all necessary assignment papers to cause any and all of said Patents to be issued to [UNM]."

We thus agree with UNM as to the contractual obligations that arose from the Patent Policy, the Co-Inventor Agreement, and the Joint Assignments. The Patent Policy's statement that the inventions "belong to" UNM and the Co-Inventor agreement's statement that UNM "is the Owner" of the inventions evince the parties clear intent that UNM would own the inventions. The Joint Assignments expressly vest ownership of the parent applications in UNM. Furthermore, all of those documents imposed upon Scallen and Knight a continuing duty to cooperate in the prosecution of patent applications, which expressly includes "signing ... patent applications and associated documents" an "execut[ing] all necessary assignment papers." We find the broad language contained in the Patent Policy, the Co-Inventor Agreement, and the Joint Assignments more than sufficient to obligate Scallen and Knight to assign to UNM their beta-alethine and vitaletheine inventions and *all* related patents and applications, including the CIP applications. *See Univ. of W. Va.*, 278 F.3d at 1298, 61 USPQ2d 1454-55 (recognizing a student's obligation to assign an invention to a university based on a policy providing that the university owns all inventions that are made by university personnel or made with substantial use of university resources); *Chou v. Univ. Chi.*, 254 F.3d 1347, 1357, 59 USPQ2d 1257, 1261 (Fed.Cir.2001) (concluding under Illinois law, that a graduate student was obligated to assign her inventions to

the university under its patent policy even absent a signed contract requiring such assignment).

Moreover, both Scallen and Knight acted as though they intended to be bound by the Patent Policy. Scallen and Knight, who had assigned earlier unrelated inventions to UNM, do not suggest that they were unaware of the Patent Policy. On the contrary, they acted in accordance with the terms and conditions of the Patent Policy and the Co-Inventor Agreement: for example, they submitted invention disclosure statements to UNM in 1986 and they assigned the five parent applications to UNM in 1991. It was not until a dispute concerning the prosecution of the vitaletheine applications arose that Scallen and Knight refused to cooperate with UNM. Until that point, Scallen and Knight had acted as though they were obligated to assign their inventions to UNM and to cooperate in the prosecution of related patent applications.

Based on the language of the Patent Policy, the Co-Inventor Agreement, and the Joint Assignments, as well as Scallen and Knight's conduct, we conclude that Scallen and Knight were contractually obligated to assign to UNM the beta-alethine and vitaletheine inventions, including all related patents and applications, and to cooperate in the prosecution of those applications. It is not disputed that Scallen and Knight refused to assign the CIP applications to UNM. Thus, there is no genuine issue of material fact and it is clear that they have violated their contractual obligation to assign the beta-alethine and vitaletheine inventions, including all related patents and applications, to UNM. We therefore conclude that the district court did not err in granting summary judgment in favor of UNM on Count IV.

B. *Ownership*

Scallen and Knight make other arguments that they are the rightful owners of the beta-alethine and vitaletheine patents and applications. In addition to denying that he and

Knight had any contractual obligation to assign their inventions to UNM, Scallen argues that he and Knight are the rightful owners of the 1992 CIP applications because the Manual of Patent Examining Procedure ("MPEP") § 306 requires new assignments for CIP applications. Additionally, Scallen and Knight accuse UNM of inequitable conduct, arguing that UNM did not have power of attorney from the inventors to prosecute the patents and that UNM unlawfully used Scallen and Knight's 1992 inventor declarations to support the amendments changing the structures in the vitaletheine applications.

UNM responds that it either is the owner or is entitled to be the owner of the beta-alethine and vitaletheine patents and applications because Scallen and Knight were contractually obligated to assign their inventions to UNM.

1. *The Beta-Alethine Patents and Applications*

We agree with UNM that the district court did not err in granting summary judgment that UNM is the owner or is entitled to ownership of the beta-alethine patents and applications. As discussed above, Scallen and Knight were contractually obligated to assign the patents and applications to UNM. UNM is therefore entitled to be the rightful owner of the beta-alethine patents and applications.

Scallen and Knight's further arguments to the contrary are without merit. First, we reject Scallen and Knight's claim of ownership based on the argument that MPEP § 306 requires new assignments for CIP applications. The MPEP sets forth PTO procedures; it is not a statement of law. *Molins PLC v. Textron, Inc.*, 48 F3d. 1172, 1180 n. 10, 33 USPQ2d 1823, 1828 n. 10 (Fed.Cir.1995). Moreover, MPEP § 306 refers to a PTO requirement for issuing a patent from a CIP application to an assignee; it does not alter the legal ownership rights in patent applications and issued patents. Secondly, Scallen and Knight have not put forth any evidence of inequitable conduct in UNM's prosecution of the

patent applications, which is what would be relevant to inequitable conduct. In any event, even if inequitable conduct before the PTO were proved, it would not affect UNM's right to the patents and applications as against Scallen and Knight, but would affect only their enforceability. *Univ. of W. Va.*, 278 F.3d at 1301-02, 61 USPQ2d at 1457. Scallen and Knight have thus failed to show any genuine issue of material fact that UNM's claim of ownership of the beta-alethine patents and applications is flawed. We therefore conclude that the district court did not err in declaring UNM to be entitled to ownership of the beta-alethine patients and applications or in granting summary judgment to UNM on Count II.

2. *The Vitaletheine Patents and Applications*

With respect to the vitaletheine inventions, Scallen and Knight deny that they are the inventors of the subject matter in the patients and applications because UNM allegedly added new matter to the CIP applications during prosecution by amending the chemical structures of two compounds. Scallen and Knight argue that Murray and Wallace synthesized the compounds in a manner different from that prescribed by Scallen and Knight, that the chemical and physical characteristics of the original compounds differ from those of the amended compounds, and that the original and amended compounds differ in biological efficacy. Scallen and Knight thus argue that they have no duty to assign what they did not invent and that the '313 and '536 patents, which contain the amended structures, are invalid.

UNM responds that the district court correctly determined that no new matter was added by amendment in the vitaletheine applications, arguing that a structural formula may be corrected without violation of 35 U.S.C. § 132 if there is sufficient evidence to show that the added structure is an inherent and more accurate description of the disclosed subject matter. UNM further argues that

substantial evidence supports the court's detailed factual findings that Murray and Wallace followed the exact method of synthesis disclosed in the patent applications and determined the correct structures for the two vitaletheine compounds. UNM also adverts to the presumption of correctness and validity arising from, respectively, the PTO's determination that the amendments did not add new matter and its issuance of the of the '313 and '536 patents.

We agree with UNM that the district court did not err in declaring UNM to be entitled to ownership of the vitaletheine patents and applications. As assignee of the vitaletheine inventions, UNM was entitled to prosecute the applications and to make amendments during prosecution. Scallen and Knight were contractually obliged to assist UNM in the prosecution of any and all patent applications relating to their inventions. Their refusal to do so did not impair UNM's right to continue prosecution. Accordingly, UNM acted reasonably in relying on Murray and Wallace, both experts in organic chemistry, to verify the accuracy of the descriptions of the inventions as disclosed in the patent applications and amendments. As the district court found based on the evidence before it, Murray and Wallace synthesized the vitaletheine compounds according to Scallen and Knight's descriptions before concluding that two of Scallen and Knight's chemical structures were incorrect.

UNM's subsequent amendments to the vitaletheine applications, based on Murray and Wallace corrected structures, did not alter the inventorship or ownership rights in those applications and the resulting patents. The amendments did not describe different inventions; they only clarified and corrected the erroneous characterization of the already disclosed inventions. Such amendments do not add to or change the nature of the disclosed inventions. As one of our predecessor courts wrote:

> From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the

> same thing. The graphic formulae and the chemical nomenclature, the systems of classification and study such as the concepts of homology, isomerism, etc., are mere symbols by which compounds can be identified, classified, and compared. But a formula is not a compound and while it may serve in a claim to identify what is being patented, as the metes and bounds of a deed identify a plot of land, the thing that is patented is not the formula but the compound identified by it.

In re Papesch, 50 C.C.P.A. 1084, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963). Indeed, a chemical structure is simply a means of describing a compound; it is not the invention itself. In the patents and applications at issue, the "vitalethine V_4" and "benzyl derivative of vitaletheine" structures were Scallen and Knight's means of identifying their inventions in a manner that would be understood by others of skill in the art. The amendments changing those structures to the structures for beta-alanyl-taurine and carbobenzoxy beta-alanyl-taurine therefore did not alter the claimed inventions. Rather, they amended the specifications and claims to describe Scallen and Knight's inventions more accurately. [7] Such amendments are not new matter, and the district court did not err in its holding to that effect.

Thus, the amendments to the vitaletheine applications do not change the fact that Scallen and Knight are the inventors of the claimed inventions. Nor do they change the fact that UNM is entitled to own the vitaletheine inventions, applications, and patents, which Scallen and Knight were contractually obligated to assign. We therefore conclude that the district court did not err in declaring Scallen and Knight to be the inventors of the vitaletheine inventions (*i.e.*,

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[7] We need not enter the scientific dispute over whether the amended structures actually describe the vitaletheine inventions correctly, as that question has no bearing on the inventorship and ownership issues before us.

Count III) or in declaring UNM to be the owner of the vitaletheine patents and applications (*i.e.*, Count I).

C. *The Eleventh Amendment*

On appeal, Scallen and Knight argue that the district court erred in allowing UNM to withdraw its claims for money damages and in subsequently dismissing their counterclaims. Scallen and Knight assert that UNM waived its Eleventh Amendment immunity as to any claims in recoupment when it filed suit with claims for money damages. They contend that there is no legal authority to support the restoration of UNM's previously waived immunity upon UNM's dismissal of its claims for money damages.

UNM responds that the district court properly granted UNM's motion to dismiss Scallen and Knight's counterclaims. It argues that it has not waived its Eleventh Amendment immunity from money damages by filing suit because it now seeks only declaratory and injunctive relief. UNM also argues that the issue as to whether the court properly allowed UNM to amend its complaint is moot because the court did not award any money damages to UNM and consequently Scallen and Knight had no damages to recoup. UNM further argues that the court did not abuse its discretion in allowing UNM to amend its complaint and that UNM's claim for attorney fees and costs did not waive its immunity for damages.

1. *UNM's Withdrawal of Its Request for Money Damages*

We agree with UNM that the district court did not abuse its discretion in permitting amendment of the complaint to withdraw any request for money damages. We apply regional circuit law to a trial court's procedural decisions that relate to issues not unique to our exclusive jurisdiction. *See Midwest Indus.*, 175 F.3d at 1359, 50 USPQ2d at 1675. Under Tenth Circuit law, a trial court's grant of leave to amend a pleading is reviewed for an abuse of discretion.

Gillette v. Tansy, 17 F.3d 308, 312 (10th Cir.1994). Federal Rule of Civil Procedure 15(a) provides that leave to amend a pleading "shall be freely given when justice so requires." Under Tenth Circuit law, a court should generally deny leave to amend only upon a showing of "undue delay, undue prejudice to the opposing party, bad faith or dilatory motive, failure to cure deficiencies by amendments previously allowed or futility of amendment." *Frank v. U.S. West, Inc.*, 3 F.3d 1357, 1365 (10th Cir.1993) (citation omitted). None of those grounds exists here. The court's permission for UNM to withdraw its claims for monetary relief in fact supports the public interest in reducing litigation. We therefore conclude that the court did not abuse its discretion in granting UNM leave to amend its complaint.

2. *Dismissal of Counterclaims*

Before reviewing the district court's dismissal of Scallen and Knight's counterclaims for money damages, we must first determine whether to apply Tenth Circuit law or Federal Circuit law to the question of UNM's Eleventh Amendment waiver. Keeping in mind the policy interests both in "bring[ing] about uniformity in the area of patent law" and in "minimizing confusion and conflicts in the federal judicial system," *Manildra Milling Corp. v. Ogilvie Mills, Inc.*, 76 F.3d 1178, 1181, 37 USPQ2d 1707, 1709 (Fed.Cir.1996) (citations omitted), we resolve the issue by deciding that the question of Eleventh Amendment waiver is a matter of Federal Circuit law. We do so because the goal of promoting national conformity in patent law would best be served by applying our own law. Were we to apply regional circuit law, the counterclaims that a defendant in a state-initiated patent suit would be entitled to assert, and for which the state would be potentially liable, might vary with the regional circuit in which the case originated. Application of our own law, however, would ensure uniformity concerning which counterclaims may be asserted against a state that seeks to litigate its patent rights in federal

court. In fact, as discussed below, there is a noted lack of uniformity among the regional circuits regarding the scope of a state's Eleventh Amendment waiver through litigation conduct. Applying our own law would ensure uniformity when patent issues are litigated. In light of these considerations, we hold that the issue of Eleventh Amendment waiver before us is a matter of Federal Circuit law. We apply a *de novo* standard of review to this question of law. [8]

Turning to the merits, we conclude that the court erred in dismissing all of Scallen and Knight's counterclaims for money damages on the ground of the Eleventh Amendment. The district court noted, and the parties do not dispute, that UNM is considered to be an "arm of the state" and therefore is generally entitled to Eleventh Amendment immunity. *Dismissal of Counterclaims* at 3 (citing *Buchwald v. University of New Mexico School of Medicine*, 159 F.3d 487, 494 n. 3 (10th Cir.1998)). However, it has long been established that a state waives its Eleventh Amendment immunity when it consents to federal court jurisdiction by voluntarily appearing in federal court. *Clark v. Bernard*, 108 U.S. 436, 447, 2 S.Ct. 878, 27 L.Ed. 780 (1883); *see also Gunter v. Atl. Coast Line R.R.*, 200 U.S. 273, 284, 26 S.Ct. 252, 50 L.Ed. 477 (1906) ("[W]here a State voluntarily becomes a party to a cause and submits its rights for judicial determination, it will be bound thereby and cannot escape the result of its own voluntary act by invoking the prohibition of the Eleventh Amendment." (citation omitted)). As UNM unmistakably consented to federal court jurisdiction when it filed suit against Scallen and Knight, the question before us is the extent to which UNM waived its Eleventh Amendment immunity by that action.

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[8] The regional circuits uniformly agree that Eleventh Amendment waiver is a question of law subject to *de novo* review.

UNM argues that the district court correctly determined that UNM waived its immunity only with respect to counterclaims in recoupment, *i.e.*, counterclaims that arise from the same transaction or occurrence as the state's claims, seek relief of the "same kind or nature" as do the state's claims, and seek an amount not greater than the amount sought in the state's claims. *See Dismissal of Counterclaims* at 3 (citation omitted). [9] We do not agree; UNM did waive its immunity at least with respect to certain counterclaims at issue here.

The first question we must resolve, however, is whether recoupment is the best criterion for determining the extent of waiver. Although some courts have applied the recoupment theory to a state's waiver of its Eleventh Amendment immunity, *see, e.g., In re Friendship Med. Ctr., Ltd.*, 710 F.2d 1297, 1301 (7th Cir.1983); *see also* 3 James Wm. Moore, *Moore's Federal Practice* § 13.50[4] (3d ed.2002) (collecting district court cases), other courts have deemed that a state that voluntarily appears in federal court has waived its immunity for all compulsory counterclaims, *see, e.g., In re Lazar*, 237 F.3d 967, 978 (9th Cir.2001); *In re Creative Goldsmiths of Wash., D.C., Inc.*, 119 F.3d 1140, 1149 (4th Cir.1997). For the reasons discussed below, we think that the latter position is the better view. [10]

The range of compulsory counterclaims is broader than counterclaims in recoupment, which are a subset of compulsory counterclaims. Recoupment counterclaims are

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[9] The case primarily relied on by the district court, *FDIC v. Hulsey*, 22 F.3d 1472 (10th Cir.1994), involved a question of the *federal* sovereign's immunity from suit, not a *state's* immunity under the Eleventh Amendment. *See id.* at 1486-87.

[10] Although we addressed a similar issue in *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 27 USPQ2d 1241 (Fed.Cir.1993), the facts of that case did not require us to distinguish between compulsory counterclaims and those in recoupment. *See id.* at 946-48, 998 F.2d 931, 27 USPQ2d at 1251-53.

limited to counterclaims of the "same kind or nature" and, if monetary, are limited to the amount of the principal claims against which they constitute recoupment. *FCIC v. Hulsey*, 22 F.3d 1472, 1487 (10th Cir.1994). However, compulsory counterclaims, while being limited to those that arise from the same transaction or occurrence, allow for adjudication of counterclaims that are not strictly of the "same kind or nature," but should be litigated together. In particular, counterclaims for royalties under an agreement relating to patents should be litigated in the same cause of action as a claim for a declaration of ownership of those patents, and the state should be considered to have consented to such.

Recently, in *Lapides v. Board of Regents of the University System of Georgia*, 535 U.S. 613, 122 S.Ct. 1640, 152 L.Ed.2d 806 (2002), the Supreme Court addressed the inconsistency and unfairness that could result from allowing a state that voluntarily avails itself of the federal courts to simultaneously claim immunity under the Eleventh Amendment. [11] The Court explained:

> It would seem anomalous or inconsistent for a State both (1) to invoke federal jurisdiction, thereby contending that the "Judicial power of the United States" extends to the case at hand, and (2) to claim Eleventh Amendment immunity, thereby denying that the "Judicial power of the United States" extends to the case at hand. And a Constitution that permitted States to follow their litigation interests by

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[11] The *Lapides* Court held that a state waives its Eleventh Amendment immunity when it removes a case from state court to federal court. 122 S.Ct. at 1646. Although the state in that case attempted to assert its Eleventh Amendment immunity for the very claim that it brought into federal court, whereas UNM seeks to invoke its Eleventh Amendment immunity for counterclaims asserted against it, the principles articulated by the Court in its opinion are both applicable and instructive.

> freely asserting both claims in the same case could generate seriously unfair results.

Id. at 1643.

That rationale applies to the facts of the present case, in which "seriously unfair results" could obtain if a state were permitted to file suit in federal court seeking to enforce a right to ownership of patents arising from certain contractual agreements and conduct and, at the same time, to claim immunity from liability for royalties or other compensation arising from those same contracts and conduct. While such counterclaims might not be of the "same kind or nature" as a claim to ownership of the patents, they surely would be compulsory counterclaims. Thus, at least under the facts of this case, the compulsory counterclaim criterion is superior to the recoupment criterion for determining waiver of immunity with respect to counterclaims. Moreover, because a state as plaintiff can surely anticipate that a defendant will have to file any compulsory counterclaims or be forever barred from doing so, it is not unreasonable to view the state as having consented to such counterclaims. We thus hold that when a state files suit in federal court to enforce its claims to certain patents, the state shall be considered to have consented to have litigated in the same forum all compulsory counterclaims, *i.e.*, those arising from the same transaction or occurrence that gave rise to the state's asserted claims. Accordingly, we conclude that by filing suit for a declaration of patient ownership and inventorship based on certain contracts and conduct, UNM waived its Eleventh Amendment immunity with respect to all compulsory counterclaims arising from those contracts and conduct.

We next consider the question of which of Scallen and Knight's counterclaims for money damages are compulsory. To begin with, as indicated above, both UNM's right to patent ownership and the inventors' right to any royalties that may be due from the patents at issue clearly arise from

the same transaction or occurrence, *viz.*, the assignment of the patent rights. Specifically, the UNM Patent Policy, which provides that UNM is the owner of the inventions and patents at issue, also states that the inventors "shall receive a percentage of any income which the University obtains for the exploitation of the invention, such percentage to be determined by negotiation between the President [of UNM] and the inventor[s]." Because Knight's counterclaim for royalties arises from the same contracts on which UNM's claim of patent ownership is based, that counterclaim is compulsory. We thus conclude that the district court improperly dismissed Knight's counterclaim for royalties as barred by the Eleventh Amendment; accordingly, we reverse that decision.

With regard to the other counterclaims for money damages advanced by Scallen and Knight, they apparently include Scallen's counterclaims for breach of the duties of care, good faith, and fair dealing; breach of duty; and damages resulting from the conduct, acts, and omissions of UNM; as well as Knight's counterclaims for breach of contract; intentional interference with prospective economic advantage; malicious abuse of process; slander of inventorship; breach of fiduciary duty. Because of the lack of specificity in these *pro se* pleadings and the minimal discussion of the counterclaims in the record, we are unable to discern with confidence which of them are compulsory. Therefore, recognizing the *pro se* status of Scallen and Knight and in order to ensure that the interests of justice are served, we vacate the district court's dismissal of those counterclaims and remand for the court to determine which counterclaims arise from the same transaction or occurrence as do UNM's claims for breach of contract, declaration of patent ownership, and declaration of inventorship. Those that the court determines to be compulsory counterclaims should not be barred by the Eleventh Amendment. Only those counterclaims that are not compulsory should be dismissed. Scallen and Knight are admonished, however, to

be precise in indicating to the district court how they were damaged by actions or inactions arising from the same transactions. None of the above should preclude the district court from dismissing any counterclaims on proper grounds other than the Eleventh Amendment.

In sum, we reverse the district court's Eleventh Amendment dismissal of Knight's counterclaim for royalties. We vacate the court's dismissal of Scallen and Knight's other counterclaims for money damages, and we remand for the district court to determine which, if any, of those counterclaims are compulsory in adjudication of UNM's claims asserted in Counts I-IV and therefore should not have been dismissed on the ground of the Eleventh Amendment.

D. *Appointment of a Special Master*

On appeal, Scallen and Knight contest the district court's *sua sponte* appointment of a special master. They argue that the appointment does not meet the "exceptional circumstances" requirement of Federal Rule of Civil Procedure 53(b), as interpreted by the Supreme Court in *La Buy v. Howes Leather Co.*, 352 U.S. 249, 77 S.Ct. 309, 1 L.Ed.2d 290 (1957). Scallen and Knight also argue that the district court's *sua sponte* appointment, just four days after UNM moved for the appointment of a special master, and the court's failure to consult Scallen or Knight prior to the appointment deprived them of an opportunity to object. Scallen and Knight further argue that the use of a special master for the sole purpose of reviewing pending motions is contrary to Article III of the Constitution. Finally, Scallen and Knight assert that Special Master Regan had a potential conflict of interest or bias because he had taught classes at UNM's law school.

UNM responds that Scallen and Knight waived their right to object to the appointment of a special master by not objecting until after the special master's second report was

filed. UNM argues that a court may appoint a special master without the consent of the parties and that a special master need not have expertise in the subject technology. Additionally, UNM responds that Regan cannot be held to have been biased simply because he found Scallen and Knight's legal theories to be flawed.

The district court appointed the special master on March 21, 2000 and issued the order of reference the following day. Scallen filed a response to the appointment in which he stated that he was "hopeful that the Special Master [would] be successful in his endeavors." The only reservation that Scallen expressed at that time was that he would like the special master to conduct any hearings telephonically. The special master eventually issued two reports: one was dated May 31, 2000 and adopted by the court on August 9, 2000; the other was dated September 20, 2000 and adopted by the court on January 29, 2001. It was not until February 5, 2001 that Scallen requested revocation of both the special master's appointment and the order of reference.

We thus agree with UNM that Scallen and Knight waived any objection they might have had to the court's appointment of a special master. It is well-settle that objection to the appointment and use of a special master may be waived if not made in a timely fashion. *E.g., Clark v. Poulton*, 963 F.2d 1361, 1367 (10th Cir.1992); *First Iowa Hydro Elec. Coop. v. Iowa-Ill. Gas & Elec. Co.*, 245 F.2d 613, 628 (8th Cir.1957). A party may not wait to see whether it likes a master's findings before challenging the use of a master. *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1566, 7 USPQ2d 1057, 1061 (Fed.Cir.1988). Scallen and Knight did not object to the special master's appointment for nearly a year, and Scallen then did so only after the special master had issued two reports with findings and recommendations unfavorable to them. Even recognizing that Scallen and Knight are *pro se* litigants, we find that they had ample opportunity to object well before they did. We therefore

conclude that Scallen and Knight waived their right to object to that appointment of the special master.

E. *Costs*

In light of our remand for further proceedings in this case, we vacate the court's award of costs and special master's fee to UNM as premature. On remand, the district court may revisit the award of costs and fees once it has adjudicated the remaining issues in the case.

F. *Motion to Strike Portions of Knight's Appendix*

UNM has filed a motion to strike portions of the appendix submitted by Knight. Knight has responded. The motion to strike is moot.

CONCLUSION

The district court correctly granted summary judgment that Scallen and Knight breached their contractual obligation to assign their patents and applications to UNM. The court also correctly granted summary judgment declaring UNM to be the owner of the beta-alethine patents and applications and correctly determined that UNM is the owner of the vitaletheine patents and applications. The court erred, however, in dismissing Scallen and Knight's counterclaims for money damages as barred by the Eleventh Amendment. We reverse the court's dismissal of Knight 's counterclaim for royalties, and we vacate the court's dismissal of Scallen and Knight's other counterclaims with instructions for the district court on remand to dismiss under the Eleventh Amendment only those counterclaims that are not compulsory to UNM's claims in Counts I-IV. We also conclude that Scallen and Knight waived any objection they might have had to the appointment of a special master. Finally, we vacate the court's award of costs and the special master's fee. Accordingly, the decision of the district court is

AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED -IN-PART, *and* REMANDED.

[Decision of the district court in *Regents of the Univ. of N.M. v. Knight*, No. CIV-99-577, September 10, 2001.]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

THE REGENTS OF THE UNIVERSITY
OF NEW MEXICO

I Plaintiff,

vs. No. CIV 99-577 JC/WWD

GALEN D. KNIGHT, an individual;
and TERENCE J. SCALLEN, an individual

Defendants.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

THIS MATTER comes before the Court after a bench trial that commenced on June 25, 2001, and concluded on July 3, 2001. After considering the evidence, oral arguments, and written briefs, the Court makes the following Findings of Facts and Conclusions of Law.

FINDINGS OF FACT

A. Jurisdictional Facts

1. The Plaintiff University of New Mexico ("UNM") is a corporate body established under the Constitution and laws of the State of New Mexico.
2. Defendant Galen D. Knight, Ph.D. is a resident of the State of New Mexico.

3. Defendant Terence J. Scallen, MD., Ph.D. is a resident of the State of California.

4. The allegations of Counts I and III raise issues that arise under the Patent Laws, 35 U.S.C. § 1 *et seq.* Count III of the Amended Complaint arises under 35 U.S.C. § 256 and 28 U.S.C. § 2201.

B. Procedural History

5. The Court entered summary judgment in favor of Plaintiff on Count II of the Complaint, holding that the University is the owner of all right, title, and interest in and to the Beta-Alethine Patents and Applications (as defined in the Amended Complaint).

6. The Court entered summary judgment on Count IV, holding that Defendants Knight and Scallen breached their contractual obligations with the University by failing to execute assignments to the Vitaletheine Patents and Applications and Beta-Alethine Patents and Applications (as defined in the Amended Complaint).

7. The Court entered summary judgment holding that Defendants are the only joint inventors of one of the Vitaletheine Issued Patents, U.S. Patent No. 5,370,868 (Count III).

8. The Court dismissed Counts V, VI, and VII of the Amended Complaint.

C. Patents and Patent Applications

9. The patent application (Serial No. 08/317,548) that matured into United States Patent No. 5,578,313 (the "'313 Patent"), entitled "Therapeutic Uses of Vitaletheine Modulators in Neoplasia," was filed on October 4, 1994, as a divisional application of Application Serial No. 07/928,725, filed on August 12, 1992. The '313 Patent was issued on November

26, 1996, with Defendants Knight and Scallen listed as inventors. Defendants Knight and Scallen signed a declaration of Inventorship stating that they were the joint inventors of the subject matter claimed in Application Serial No. 07/928,725.

10. The patent application (Serial No. 08/463,732) that matured into United States Patent No. 6,096,536 (the "'536 Patent"), entitled "In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine or Carbobenzoxy-Beta-Alanyl-Taurine," as amended, was filed on June 5, 1995, as a continuation application of United States Application Serial No. 07/941,926. The '536 Patent was issued on August 1, 2000, with Defendants Knight and Scallen listed as inventors. Defendants Knight and Scallen signed a declaration of Inventorship stating they were joint inventors of the subject matter claimed in Application Serial No. 07/941,926.

11. The United States Patent Application Serial No. 08.463,784 (the "'784 Application,") entitled " In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine," as amended, was file on June 5, 1995, as a continuation application of a divisional application of Application Serial No. 07/941,926, with Defendants Knight and Scallen named as inventors. The '784 Application is pending before the United States Patent and Trademark Office ("USPTO"). Defendants signed a declaration of Inventorship as to Application Serial No. 07/941,926.

12. United States Patent Application Serial No. 08/466,143 (the"'143 Application"), entitled "Use of Vitaletheine Modulators in the Prophylaxis and Treatment of Diseases," was filed on June 6, 1995, as a continuation of Application Serial No. 07/910,892, with Defendants Knight and Scallen named as inventors. The '143 Application is pending before

the USPTO. Defendants signed the declaration of Inventorship regarding the United States Application No. 07/910,892.

13. United States Patent Application Serial No. 08/469,697 (the '"697 Application"), entitled "Use of Vitaletheine Modulators in the Prophylaxis and Treatment of Diseases," was filed on June 6, 1995, as a continuation of Application Serial No. 07/910,892, naming Defendants Knight and Scallen as the inventors. The '697 Application is pending before the USPTO. Defendants signed a declaration of Inventorship regarding the United States Application No. 07/910,892.

14. The '313 Patent, the'536 Patent, the '784 Application, the '143 Application, and the '697 Application are collectively referred to as the "Patents and Applications."

D. Amendments to the Patents and Applications

15. Plaintiff made amendments to the molecular structures of certain organic compounds disclosed and claimed in the specifications of the Patents and Applications. The amendments were made subsequent to the filing of the applications during the ordinary course of prosecution.

16. Plaintiff amended the Patents and Applications by correcting the molecular structure of "vitaletheine V_4" with the molecular structure named "beta-alanyl-taurine" (the "beta-alanyl-taurine Amendment").

17. Plaintiff also amended the Patents and Applications by correcting the molecular structure of "benzyl derivative of vitaletheine" with the molecular structure named "carbobenzoxy beta-alanyl-taurine" (the "carbobenzoxy beta-alanyl-taurine Amendment").

18. The USPTO initially rejected the beta-alanyl-taurine Amendment and the carbobenzoxy beta-alanyl-taurine Amendment to the Patents and Applications based on new matter.

19. The USPTO, however, subsequently accepted the beta-alanyl-taurine Amendment and the carbobenzoxy beta-alanyl-taurine Amendment in both the specification and claims to the Patents and Applications after further review. Three examiners of the USPTO, all knowledgeable in the necessary technology, accepted as true and accurate the beta-alanyl-taurine Amendment and the carbobenzoxy beta-alanyl taurine Amendment as containing subject matter that is neither new nor in contravention of the Patents Laws, including the prohibition against new matter under 35 U.S.C. § 132.

20. The beta-alanyl-taurine Amendment and the carbobenzoxy beta-alanyl-taurine Amendment deleted the vitaletheine modulator structures from the claims.

21. Defendants disagree with the Amendments and maintain that the structures as set forth in the Patents and Applications prior to the Amendments are the correct molecular structures for the organic compounds.

22. Defendant Knight filed protests and other documents with the USPTO regarding the Amendments.

23. No amendment was made to the specification of the application maturing into U.S. Patent No. 5,370,868 that altered the molecular structure of any compound disclosed in the application as filed.

E. Synthesis of the Compounds

24. Dovetail Technologies, Inc. ("Dovetail") is a licensee of the Plaintiff. Dovetail retained Hauser Chemical Research, Inc. ("Hauser"), under the direction of Christopher Murray, Ph.D., ("Dr. Murray"), to synthesize vitalethine, vitaletheine V_4, and the benzyl derivative of vitaletheine, for use in preclinical studies and clinical trials by Dovetail.

25. Dr. Murray is an expert in both synthetic organic chemistry and in process chemistry development of organic compounds.

26. The Food and Drug Administration licensed Hauser to make synthetic organic compounds for use as active pharmaceutical ingredient materials. Hauser has made numerous different active pharmaceutical ingredient materials in compliance with Good Manufacturing Practice standards required by the Food and Drug Administration.

27. Hauser, under Dr. Murray's directorship, employs the following analytical techniques to analyze and characterize organic compounds: one and two-dimensional carbon-13 nuclear magnetic resonance (^{13}C-NMR), proton nuclear magnetic resonance (^{1}H-NMR), electrospray mass spectroscopy elemental analysis, and infrared spectroscopy.

28. The initial synthetic procedures for vitaletheine V_4 and the benzyl derivative of vitaletheine used by Hauser and Dr. Murray followed the precise specifications and procedures described in the Patents and Applications.

29. Dr. Murray and Hauser synthesized the organic compound denoted as "the benzyl derivative of vitaletheine" using the exact synthetic specifications stated in the Patents and Applications on thirteen distinct occasions.

30. Dr. Murray and Hauser synthesized the organic compound denoted as "vitaletheine V_4" using the exact synthetic specifications stated in the Patents and Applications on five occasions.

31. The organic compounds initially synthesized by Dr. Murray and Hauser using the synthetic specifications for vitaletheine V_4 and the benzyl derivative of vitalethine as stated in the Patents and Applications had the same characteristics as the above named compounds. In addition, the organic compounds were made in accordance with the methods and steps described in the Patents and Applications and were the same organic compounds as described in the Patents and Applications, as identified by the methods of manufacture, ^{13}C-NMR data in the Patents and Applications, ^{1}H-NMR data in the Patents and Applications, and other data and descriptions in the Patents and Applications.

32. Upon synthesizing vitaletheine V_4 and the benzyl derivative of vitaletheine utilizing the specific methods as described in the Patents and Applications, Dr. Murray and Hauser then modified the synthetic methods using accepted techniques of process chemistry in order to optimize yield and manufacturing processes. Both compounds made by Dr. Murray and Hauser following the modified synthetic processes were the same organic compounds as those initially produced by Dr. Murray and Hauser utilizing the same processes as described in the Patents and Applications for vitaletheine V_4 and the benzyl derivative of

vitaletheine, as verified by various tests including one-and two-dimensional ^{13}C-NMR and ^{1}H-NMR, electrospray mass spectroscopy, elemental analysis and infrared spectroscopy. Plaintiff contends that one- and two-dimensional ^{13}C-NMR and ^{1}H-NMR is the most definitive analytical technique for analysis, characterization, and identification of organic compounds.

33. Dr. Murray and Hauser then conducted literature searches, and identified an alternative means of synthesis for the compounds based on the "Feuer method." Identifying an alternative method of synthesis and demonstrating that the same organic compound results is a recognized means of verifying the molecular structure and identity of an organic compound. Through the Feuer method, Dr. Murray and Hauser produced the exact organic compounds as those made using the methods detailed in the Patents and Applications for vitaletheine V_4 and the benzyl derivative of vitaletheine. This method proves that the molecular structures determined by Dr. Murray and Hauser for the above organic compounds as defined in the Patents and Applications are correct.

34. The organic compounds that resulted when Dr. Murray and Hauser used the exact methods described in the Patents and Applications for the synthesis of vitaletheine V_4 and the benzyl derivative of vitaletheine did not have the same molecular structures as depicted in the Patents and Applications for vitaletheine V_4 and the benzyl derivative of vitaletheine.

35. The organic compounds that Dr. Murray and Hauser synthesized using the methods depicted in the

Patents and Applications for the synthesis of vitaletheine V_4 and the benzyl derivative of vitaletheine were inherent in and the product of the methods so described in the Patents and Applications.

36. Dr. Murray and Hauser determined that vitaletheine V_4 and the benzyl derivative of vitaletheine did not have the molecular structures that Defendants assigned to them in the Patents and Applications.

F. Determination of the Amended Molecular Structures

37. In order to determine the correct molecular structures, Dr. Murray asked nationally and internationally known experts, including professors from the University of Colorado, experts at Hauser, and members of Dovetail's scientific advisory board to analyze and determine the correct molecular structures of the compounds called vitaletheine V_4 and the benzyl derivative of vitaletheine as described in the Patents and Applications.

38. Dr. Murray determined that vitaletheine V_4 should accurately be denoted as beta-alanyl-taurine and the benzyl derivative of vitaletheine should accurately be denoted as carbobenzoxy-beta-alanyl-taurine.

G. Inability to Synthesis Vitalethine

39. As described in the Patents and Applications, Dr. Murray and Hauser repeatedly made beta-alethine, the primary starting material for vitalethine. Dr. Murray and Hauser performed a formal structure proof of the resulting beta-alethine, thereby proving that the resulting compound had the same structure as the known structure of beta-alethine. This included development of a reference standard of beta-alethine, with analytical tests including two-dimensional NMR, elemental analysis, purity tests, in

addition to other tests confirming that beta-alethine was in fact made.

40. Dr. Murray and Hauser attempted, on at least twenty-six occasions, to synthesize the organic compound called "vitalethine" as described in the Patents and Applications. Dr. Murray and Hauser followed the exact methods described in the Patents and Applications, and they followed modifications thereof based on the described method of synthesis and known organic chemistry methodologies. Dr. Murray and Hauser further communicated with Defendant Knight concerning the synthetic method, and incorporated suggestions from Knight. Dr. Murray and Hauser also followed modifications in the method of synthesis as described by Defendants Knight and Scallen in a publication subsequent to the Patents and Applications. No organic compound resulted from these attempts meeting the description of "vitalethine" contained in the Patents and Applications. The primary resulting product obtained by Dr. Murray and Hauser was beta-alethine, which was the primary starting material described in the Patents and Applications used in the synthesis of "vitaletheine".

H. Confirmation of the Synthesis and Molecular Structures

41. After Hauser reported the results, Plaintiff retained an expert consulting firm, Professional Analysis, Inc. ("PAI"), under the supervision of J. Shield Wallace, Ph.D. ("Dr. Wallace"), to synthesize and characterize organic compounds in accordance with the methods described in the Patents and Applications.

42. The synthetic procedures followed by Dr. Wallace and PAI for vitaletheine V_4 and the benzyl derivative

of vitaletheine were in accordance with the methods described in the Patents and Applications.

43. The organic compounds synthesized by Dr. Wallace and PAI that resulted from the methods described in the Patents and Applications for synthesis of vitaletheine V_4 and the benzyl derivative of vitaletheine did not have the molecular structures of vitaletheine V_4 and the benzyl derivative of vitaletheine as depicted in the Patents and Applications.

44. Dr. Wallace determined that the organic compounds described as vitaletheine V_4 and the benzyl derivative of vitaletheine did not have the molecular structures assigned to those compounds by the inventors in the Patents and Applications as filed.

45. Dr. Wallace determined that vitaletheine V_4 was beta-alanyl-taurine and that the benzyl derivative of vitaletheine was carbobenzoxy-beta-alanyl-taurine.

46. Dr. Wallace and PAI attempted on three separate occasions to synthesize the organic compound called vitalethine as described in the Patents and Applications, following the exact methods therein. No organic compound resulted from these attempts meeting the description of vitalethine contained in the Patents and Applications.

47. Following the methods described in the Patents and Applications for the synthesis of vitalethine, the primary resulting product obtained by Dr. Wallace and PAI was beta-alethine.

I. Existence of Vitalethine

48. The organic compound called vitalethine in the Patents and Applications is not a part of any Amendment at issue.

49. Dr. Knight testified that he was the only person he knew of who had successfully synthesized vitalethine.

J. Structures of the Amendments are Inherent in the Patents and Applications

50. The molecular structures disclosed in the beta-alanyl-taurine Amendment and in the carbobenzoxy beta-alanyl-taurine Amendment are implicit in and are an inherent characteristic of the written disclosures and specifications as filed in each of the Patents and Applications.

L. Presumption of Correctness

51. Defendants have not overcome the presumption of correctness as to the Patents and Applications wherin the Amendments have been allowed.

CONCLUSIONS OF LAW

1. The Court has personal jurisdiction over the parties.

2. Venue is properly laid in the District of New Mexico pursuant to 28 U.S.C. § 1400(b).

3. The issues raised in this case necessarily depend on one or more substantive questions of United States Patent Law.

4. The relief sought in Count III pursuant to 35 U.S.C § 256 necessarily arises under the United States Patent Law for which federal courts have exclusive jurisdiction.

5. The Court has subject matter jurisdiction over the claims now pending.

6. The last sentence of 35 U.S.C. § 132 provides: "No amendment shall introduce new matter into the disclosure of the invention." If new matter in contravention of 35 U.S.C. § 132 is introduced during prosecution of a patent application, the claims depending on or incorporating such new matter are invalid under 35 U.S.C. § 112. See *Waldmar Link, GmbH & Co. v. Osteonics Corp.*, 32 F.2d 556, 558 (Fed. Cir. 1994); *Transco Prod., Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 558 (Fed. Cir. 1994); *SDS USA, Inc. v. Ken Specialties, Inc.*, 122 F.Supp.2d 533, 544 (D.N.J. 2000).

7. Determination of whether an amendment introduces new matter "depends on the facts of the case: the nature of the disclosure, the state of the art, and the nature of the added matter." *Brooktree Corporation v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1574 (Fed. Cir. 1993). The rule applied is "that a structural formula may be corrected without violation of 35 U.S.C. § 132, if 'there is sufficient evidence in the record to show the (proposed structure) to be an inherent characteristic of the subject matter so identified.'" *Ex parte Marsili*, 214 U.S.P.Q. 904, 906 (Bd. Pat. App. 1979) (quoting In re Magerlein, 346 F.2d 609, 611 (C.C.P.A. 1965)). The Court finds that the organic compounds described in the beta-alanyl-taurine Amendment and the carbobenzoxy beta-alanyl-taurine Amendment inherently had, when the Patents and Applications were filed, and now have, the molecular structures given in the Amendments. On multiple occasions, Plaintiff attempted the synthesis of the compounds as reflected in the Patents and Applications. Plaintiff's results reflected the organic compounds in the beta-alanyl-taurine

Amendment and the carbobenzoxy beta-alanyl-taurine Amendment. Plaintiff also was unable to create the organic compound called vitalethine. Plaintiff verified these result using different experts, tests, and methodologies. Thus, the organic compounds described, exemplified, and claimed in the Patents and Applications inherently had the molecular structures of the organic compounds as reflected in the Amendments. Accordingly, the Amendments did not add new matter.

8. Furthermore, a determination by the Patent and Trademark Office that an amendment does not introduce "new matter" as defined in 35 U.S.C. § 132 is entitled to an especially weighty presumption of correctness:

> A patent is presumed valid, and this presumption is based in part on the expertise of the patent examiners presumed to have done their job. This presumption, which may be viewed as a presumption of administrative correctness, as applied to a new matter determination was discussed by our predecessor court, which stated that "the fact that the Patent Office allows ... an amendment without objection thereto as new matter (within the meaning of 35 U.S.C. § 132) is entitled to an especially weighty presumption of correctness."

Brooktree Coporation v. Advanced Micro Devices, Inc., 977 F.2d at 1574-75; *accord, In re Smythe*, 480 F.2d 1376, 1385 n. 5, (CCPA 1973); *Technicon Instruments Corp. . Coleman Instruments, Inc.*, 255 F.Supp. 630 (N.D.Ill. 1966), *aff'd*, 385 F.2d 391 (7th Cir. 1967). In this case, a total of three different Examiners of the USPTO, each skilled in the relevant technology, have considered and accepted the beta-alanyl-taurine

Amendment and the carbobenzoxy beta-alanyl-taurine Amendment as properly filed and as containing subject matter that was not new or in contravention of the Patent Laws, including specifically the "new matter" prohibition of 35 U.S.C. § 132. In addition, the evidence shows that each Examiner in the USPTO took the question of new matter seriously, and demanded rigorous and exhaustive proof before allowing the Amendments.

9. The Amendments do not, as a matter of law, introduce "new matter" into the Patents and Applications in contravention of 35 U.S.C. § 132.

10. Defendants Knight and Scallen have failed to prove, by clear and convincing evidence, that the '313 Patent and the '536 Patent are invalid.

11. Defendants Knight and Scallen have failed to prove, by clear and convincing evidence, that the Amendments introduced "new matter" into the Patents and Applications in contravention of 35 U.S.C. § 132.

12. Defendants Knight and Scallen are the properly named and sole inventors of the Patents and Applications as amended.

13. Plaintiff is the true and lawful owner of all right, title and interest to the Patents and Applications, including the '313 Patent, the '536 Patent, the '784 Application,, the '143 Application, and the '697 Application, together with any patent or application, foreign or domestic, that is a continuation or divisional application of any of the foregoing, or which is a continuation or divisional application of a predecessor of any of the foregoing.

14. Defendant Knight and Scallen are the only, joint and properly named inventors of the '313 Patent and the '536 Patent.

15. Defendants Knight and Scallen are the only, joint and properly named inventors of the inventions disclosed in the '784 Application, the'143 Application, and the '697 Application, including without limitation the Amendments.

16. A patent is presumed valid. *See* 35 U.S.C. § 282. As Defendants contend, U.S. Patent No. 5,370,868 is therefore presumed valid. Moreover, Plaintiff is the true and lawful owner of all right, title and interest in U.S. Patent No. 5,370,868, as to which no amendment to the structure of any compound therein was made, and all other patent applications included within the Vitaletheine Patents and Applications as to which no amendment was made as to the structure of any compound included therein.

CONCLUSION

For the reasons set forth above, and based on the facts adduced at trial, the Court finds that the Amendments to the Patents and Applications in dispute, which changed the structural formula of certain compounds, do not constitute new matter in violation of 35 U.S.C. § 132. Accordingly, judgment is rendered in flavor of Plaintiff.

On a final note, when parties are unable to resolve their differences and proceed to trial, a court is forced to find for either a plaintiff or a defendant in accordance with the law. This case is troublesome because it involves a dispute, at its simplest level, over a potential cure for certain forms of cancer. While parties certainly should have an opportunity to litigate and explore the contours of their legal rights, possibly justice would be better served, at times, if a court could order the parties to cooperate and search for the

greater good in a dispute. Unfortunately, the Court does not have such discretion, and the real losers in this case are the cancer patients who must await a more promising treatment for their devastating diseases.

WHEREFORE, a judgment shall be entered in accordance with these Findings of Facts and Conclusions of Law.

s/John Edwards Conway

UNITED STATES DISTRICT JUDGE

[*Regents of the Univ. of N.M. v. Knight*, No. CIV-99-577, September 10, 2001.]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

THE REGENTS OF THE UNIVERSITY
OF NEW MEXICO

Plaintiff and Counter-defendant

vs. No. CIV-99-577 JC/WWD

GALEN D. KNIGHT, an individual,
and TERENCE J. SCALLEN, an individual,

Defendants and Counter-plaintiffs.

FINAL ORDER

THIS MATTER came on for trial before the Court, the Honorable John Edwards Conway, Senior United States District Judge, presiding, and the issues having been duly tried and findings of fact and conclusions of law having been duly rendered;

IT IS ORDERED, ADJUDGED AND DECREED:

That pursuant to this Court's Order granting partial summary judgment, filed August 9, 2000 (Doc. #191), and this Court's Order granting partial summary judgment, filed January 29, 2001 (Doc. #226), the Court declares that plaintiff The Regents of the University of New Mexico ("University") is the owner of the entire right, title and interest in and to the

following described patents and applications (the "Beta-Alethine patents and Applications"), including any and all right title and interest in and to the Beta-Alethine Patents and Applications of defendants Galen D. Knight ("Knight") and Terence J. Scallen ("Scallen"):

U.S. Patent Application No. 07/919,253, filed 7/27/92 entitled *Beta-Alethine Use in Cell Culture and Therapy*

U.S. Patent Application No. 07/924,977, filed 8/5/92, entitled *Beta-Alethine as Anti-Tumor Agent*

U.S. Patent Application No. 08/316,836, filed 10/3/94, now U.S. Patent No. 5,643,966, entitled *Beta-Alethine as Anti-Tumor Agent*

U.S. Patent Application No. 08/468,041, filed 6/6/95, entitled *Beta-Alethine Use in Cell Culture and Therapy*

U.S. Patent Application No. 08/468,043, filed 6/6/95, entitled *Beta-Alethine as Anti-Tumor Agent*

U.S. Patent Application No. 08/346,177, filed 11/22/94, entitled *Beta-Alethine Use in Cell Culture and Therapy*

European Patent Office Application No. 91912761.3, entitled *Beta-Alethine Use in Cell Culture and Therapy*

including all patents, patent applications, divisions, reissues, continuations, continuations-in-part, substitutions, renewals, and extensions thereof, in the United States and all foreign countries, and all improvements made or invented by Knight or Scallen at any time during their employment by University, including the right to bring lawsuits for past infringement of any patents that may be issued thereon, in the United States and all foreign countries, together with all right, title and interest of Knight and Scallen in and to: (a) the above inventions as described in the aforementioned applications, (b) any technical information, know-how, trade secret, process, procedure, composition, device, method, formula, protocol, technique, design, drawing or date related to the above inventions which is not covered by any

subsequently filed patent application but which is necessary at any time for practicing the above inventions, and (c) the right of priority as to such inventions under the International Convention for the Protection of Industrial Property, Inter-American Convention Relating to Patents, Designs and Industrial Models, and any other international agreements to which the United States adheres:

That the Court declares that plaintiff University is the owner of the entire right, title and interest in and to the following described patents and applications (the "Vitaletheine Patents and Applications"), including any and all right, title and interest in and to the Vitaletheine Patents and Applications of defendants Knight and Scallen:

U.S. Patent Application No. 07/910,892, filed 7/10/92, entitled *Use of Vitaletheine Modulators in the Prophylaxis and Treatment of Disease*, a continuation-in-part application of U.S. Application No. 07/549,105

U.S. Patent Application No. 07/928,725, filed 8/13/92, now U.S. Patent No. 5,370,868, entitled *Therapeutic Use of Vitaletheine Modulators in Neoplasia*, a continuation-in-part application of U.S. Application No. 07/549,440

U.S. Patent Application No. 07/941,926, filed 9/8/92, entitled *Vitaletheine and Use in Cell Cultures*, a continuation-in-part application of U.S. Application No. 07/549,438

U.S. Patent Application No. 08/317,548, filed 10/4/94, now U.S. Patent No. 5,578,313, entitled *Therapeutic Use of Vitaletheine Modulators in Neoplasia*, a divisional application of U.S. Application No. 07/928,725

U.S. Patent Application No. 08/466,143, filed 6/6/95, entitled *Use of Vitaletheine Modulators in the Prophylaxis and Treatment of Disease*, a continuing application of U.S. Application No. 07/910,892

U.S. Patent Application No. 08/321,010, filed 10/6/94, entitled *Vitaletheine and Use in Cell Cultures*, a divisional application of U.S. Application No. 07/941,926

U.S. Patent Application No. 08/463,732, filed 6/5/95, now U.S. Patent No. 6,096,536 now entitled *In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine or Carbobenzoxy-Beta-Alanyl-Taurine*, a continuing application of U.S. Application No. 08/321,010

U.S. Patent Application No. 08/463,784, filed 6/5/95, now entitled *In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine or Carbobenzoxy-Beta-Alanyl-Taurine*, a continuing application of U.S. Application No. 08/321,010

U.S. Patent Application No. 08/464,943, filed 6/5/95, entitled *Therapeutic Use of Vitaletheine Modulators in Neoplasia*, a continuing application of U.S. Application No. 08/317,548

U.S. Patent Application No. 08/469,697, filed 6/6/95, entitled *Use of Vitaletheine Modulators in the Prophylaxis and Treatment of Disease*, a continuing application of U.S. Application No. 07/910,892

European Patent Office Application No. 91915854.3, filed 7/8/91, entitled *Vitaletheine and Use in Cell Culture and Therapy*

including all patents, patent applications, divisions, reissues, continuations, continuations-in-part, substitutions, renewals, and extensions thereof, in the United States and all foreign countries, and all improvements made or invented by Knight or Scallen at any time during their employment by University, including the right to bring lawsuits for past infringement of any patents that may be issued thereon, in the United States and all foreign countries, together with all right, title and interest of Knight and Scallen in and to: (a) the above inventions as described in the aforementioned

applications, (b) any technical information, know-how, trade secret, process, procedure, composition, device, method, formula, protocol, technique, design, drawing or date related to the above inventions which is not covered by any subsequently filed patent application but which is necessary at any time for practicing the above inventions, and (c) the right of priority as to such inventions under the International Convention for the Protection of Industrial Property, Inter-American Convention Relating to Patents, Designs and Industrial Models, and any other international agreements to which the United States adheres:

That the Court declares that no new matter in contravention of 35 U.S.C. § 132, last sentence, was introduced into the Vitaletheine Patents and Applications by reason of amendments made thereto relating to the molecular structure of certain compounds disclosed and claimed therein;

That the Court declares that defendants Knight and Scallen are only joint inventors of the Vitaletheine Patents and Applications, including without limitation United States Patents No. 5,370,868, 5,578,313 and 6,096,536;

That the plaintiff University, having heretofore paid the fees of the Special Master appointed in this case pursuant to this Court's Order of Reference, filed March 22, 2000 (Doc. #110), recover the amounts paid to the Special Master from the defendants Knight and Scallen, with joint and several liability therefore, as costs of this action; and

That the plaintiff University recover its costs of action from the defendants Knight and Scallen, with joint and several liability therefore.

DATED September 10, 2001.

s/John Edwards Conway

SENIOR UNITED STATES DISTRICT JUDGE

United States Court of Appeals for the Federal Circuit

ORDER

A petition for rehearing en banc having been filed by the APPELLANT,* and the matter having first been referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on April 10, 2003.

FOR THE COURT,

s/Jan Horbaly

Clerk

Dated: April 3, 2003

cc: Terence J. Scallen, Galen D. Knight

Paul Adams

REGENTS OF UNIV. OF NM V KNIGHT, 02-1018, -1019

(DCT - 99-CV-577)

* The petition was filed by T. Scallen.

United States Court of Appeals for the Federal Circuit

ORDER

Before NEWMAN, Circuit Judge, LOURIE, Circuit Judge, and SCHALL, Circuit Judge.

A petition for rehearing having been filed by the APPELLANT*,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED.

The mandate of the court will issue on April 10, 2003.

FOR THE COURT,

s/Jan Horbaly

Clerk

Dated: April 3, 2003

cc: Terence J. Scallen, Galen D. Knight

Paul Adams

REGENTS OF UNIV. OF NM V KNIGHT, 02-1018, -1019

(DCT - 99-CV-577)

* The petition was filed by G. Knight.

CONTRACT FOR FULL-TIME SCHOOL OF MEDICINE FACULTY

Date May 16, 1986

OFFICE OF THE PRESIDENT

THE UNIVERSITY OF NEW MEXICO
ALBUQUERQUE, NEW MEXICO 87131

This contract is entered into by the University of New Mexico, hereinafter referred to as "The University", and Terence J. Scallen, M.D., Ph.D., hereinafter referred to as "Faculty Member," who is hereby appointed a full-time member of the Faculty of The University subject to conditions set forth in subsequent paragraphs.

1. The period of this contract is July 1, 1986 to June 30, 1987.

2. Faculty Member appointment status is:

Rank and Department	Tenure Code
Professor of Biochemistry	T [tenured]
Professor of Medicine	N [non-tenured]

3. Annual salary rate during this contract period is $64,500 of which all will be paid by the University. Annual salary rate includes a Special Administrative Component of $ -0- for service as: Not applicable

Should such administrative service be terminated during the period of this contract, The University reserves the right to make an appropriate adjustment in the total salry due the Faculty Member. Compensation which may be due the Faculty Member under the New Mexico Medical Foundation By-Laws will be paid on a deferred basis.

4. In the event that the Faculty Member is employed by the Veterans Administration Medical Center of Albuquerque, hereinafter, referred to as "VAMC", a portion

or all of the total salary due Faculty Member will be paid directly to Faculty Member by VAMC. Any amount to be paid by VAMC is not guaranteed by the University. In the event the VAMC component changes, The University reserves the right to make appropriate adjustment in The University component. Faculty Member agrees to sign an Authorization to Release VAMC Information which enables The University to obtain pertinent salary data concerning Faculty Member's VAMC employment.

5. Professional Liability Insurance coverage (will not) be provided for Faculty Member in accordance with the Tort Claims Act.

6. Faculty member agrees (a) to become a member of the New Mexico Medical Foundation and to sign the Individual Member Agreement; (b) to abide by the By-Laws, Individual Member Agreement, rules and regulations of the New Mexico Medical Foundation; (c) to remain a member of the New Mexico Medical Foundation for the term of this contract. Termination of membership in the New Mexico Medical Foundation for fiscal dishonesty in accordance with the procedures of the By-Laws shall automatically result in the institution of proceedings for termination of this contract. An individual terminated by the Foundation, but not by The University shall be reinstated as a member of the New Mexico Medical Foundation.

7. Faculty Member further agrees (a) to obtain and maintain in good standing such professional licensure as is required to fulfill the obligations, responsibilities, and clinical duties assigned in conjunction with this appointment by Faculty Member's Chairman or Dean; (b) to obtain and maintain in good standing professional staff appointments and clinical privileges at the VAMC and/or UNMH/BCMC and other clinical components of the UNM Medical Center and/or other health care facilities to which assigned. Failure to obtain and maintain such licensure, appointments and

privileges shall automatically result in the institution of proceedings for termination of this contract.

8. This appointment is governed by the applicable policies stated in the current *Faculty Handbook* of The University, New Mexico Medical Foundation By-Laws as amended from time to time and by applicable New Mexico state and Federal laws and regulations.

s/ Tom J. Farer, President
University of New Mexico

s/Terence J. Scallen 06/06/86
Faculty Member

[*Salary Breakdown Table Omitted]*

Please sign and return the last three copies to the Office of the Dean, School of Medicine within ten days and retain the original for your records.

200-11/85

PATENT POLICY

1. **Definitions**, as used in this statement of policy:

   a. Staff member shall mean any faculty member, student, or any other person associated with the teaching or research staffs of the University;

   b. President shall mean the President of the University or his duly authorized representative.

2. All staff members who make inventions or discoveries (i) in the course of research carried out under their direction and having all or any part of the cost paid from University funds (or funds under the control of or administered by the university), or (ii) which are the direct result of their duties with the University, or (iii) which are made in whole or in part, using University resources or facilities, shall disclose to the President all such inventions and discoveries. Except with regard to inventions and discoveries produced under the sponsorship of third parties whose requirements regarding disclosure, ownership, title, patent rights, licensing, use and royalties are different from those of the University, such inventions and discoveries belong to the University.

3. **Duty of Cooperation.** Each staff member who makes an invention or discovery covered by either parts (i), (ii) or (iii) of section 2 above, has a duty to cooperate fully with the University, or such other party as may be designated by the University, at no expense to the staff member, in all reasonable and lawful acts required to permit full exploitation of the invention or discovery. Such cooperation shall include, without limitation of the generality of the foregoing, maintaining confidentiality of the invention or discovery to the extent required to protect the owner's rights in the invention or discovery; providing information needed for preparation of patent applications and associated documents; review and signing of patent applications and

associated documents; providing information and know-how required to allow optimum use of the invention or discovery; and providing testimony needed in any administrative or judicial proceeding concerning any such invention or discovery.

4. Patent Policy Subcommittee. The Patent Policy Subcommittee shall be appointed by the Research Policy Committee and shall consist of five members of the faculty and/or non-academic staff. In considering a specific case, the Patent Policy Subcommittee may appoint one or two consultants who, in the judgment of the Subcommittee, have specialized knowledge in the area being considered.

5. Procedure. Upon a disclosure by a staff member to the President, the following procedure shall be followed:

a. In the case of any invention or discovery which initially belongs to the University under the provisions of section 2 above, the President shall decide within a reasonable time whether the University will seek to exploit the same for production of income. If the President decides that the University will not seek to exploit the invention or discovery for production of income the University shall promptly assign its title thereto to the discoverer or inventor, unless such assignment is precluded by any applicable agreement between the University and any outside agency relating to sponsored research, or is precluded by applicable government regulations.

b. The inventor shall receive a percentage of any income which the University obtains from the exploitation of the invention, such percentage to be determined by negotiation between the President and the inventor. As compensation for management costs incurred by the University, for any invention for which the University does not use an outside

patent management agent, the University shall receive 40% of any such income, prior to any division of income through such negotiations. For the protection of the inventor, however, a minimal percentage for the inventor (of the remaining 60%) will be in accordance with the following schedule:

		Percentage of Net Income
First	$1,000	100%
Next	$4,000	90%
Following	$15,000	75%
Over	$20,000	50%

c. If there is a disagreement on the negotiated division of the funds between the University and the inventor, either the inventor or the President may refer this matter to the Patent Policy Subcommittee for consideration and recommendation to the parties.

d. The Patent Policy Subcommittee shall make its recommendations within four weeks of the time the matter is referred to it.

e. In making its recommendation to the parties, the Patent Policy Subcommittee shall consider all of the various equities involved.

6. Co-Inventors. Inventions conceived by more than one inventor shall be dealt with on the same basis as those conceived by a single inventor. As between themselves, however, co-inventors shall be free to agree to any division of income. Advance written arrangements for such division may be made between the interested parties.

7. Use of Funds. Insofar as reasonably possible, funds received by the University as a result of commercial development of discoveries or inventions shall be used to sponsor additional research.

8. Best Efforts. The University shall use its best efforts to ensure, and shall require of the patent management agent a commitment to use its best efforts to ensure prompt protection for and commercial development of inventions and discoveries covered by this policy.

9. University Use of Patents. The University shall reserve the right insofar as possible to produce for its own use items patented under any of the provisions above. Such use shall be royalty free.

10. Negotiations with outside Agencies. Negotiations with outside agencies shall be carried on in such a way as to obtain for the University the maximum possible rights. None of the provisions of this policy shall be interpreted in such a way as to preclude the making of, or to limit the terms of, an agreement with an outside agency relating to sponsored research.

From: *UNM Faculty Handbook, Edition of 8/1/83.*

Joint Assignment

Whereas (names, addresses) Galen D. Knight, 1116 Gold, SW, Albuquerque, New Mexico 87102, and Terence J. Scallen, 7412 El Morro Rd., NE, Albuquerque, New Mexico 87110 hereinafter referred to as "Assignors") are employees of the University of New Mexico (hereinafter referred to as "Assignee") have made a certain invention entitled THERAPEUTIC USE OF VITALETHEINE MODULATORS IN NEOPLASIA for which a patent application was filed at the expense of the Assignee on July 6, 1990 in the United States Patent and Trademark Office. The patent application is identified as SN 07/549,440 filed on July 6, 1990.

Whereas under its stated policy Assignee is legally entitle to and is desirous of obtaining the entire right, title, and interest in and to said invention and to any patents that may be issued thereon in the United States or in any and all foreign countries;

Now, therefore, in view of the above premises and good and valuable consideration the receipt whereof is hereby acknowledged, Assignors do hereby sell, assign, and transfer unto Assignee all right, title, and interest in and to the invention in the United States and in any and all foreign countries and the entire right, title, and interest in and to any and all patents which may be issued thereon in the United States and in any and all foreign countries and in and to any and all divisions, reissues, continuations, and extensions thereof.

Assignors thereby authorize and request the Patent and Trademark Office officials to issue said Patents, when granted, to Assignee for the sole use and enjoyment of Assignee, its successors, and assigns.

Further, Assignors agree to communicate to Assignee any facts known to them respecting said invention, and to

testify in any legal proceedings, to sign all lawful papers, to execute all divisions, continuations, substitutions, renewal, and reissue applications, to execute all necessary assignment papers to cause any and all of said Patents to be issued to Assignee, to make all rightful oaths and generally to do everything necessary or desirable to aid Assignee, its successors, and assigns to obtain and enforce proper protection for said invention.

Assignors hereby covenant that no assignment, sale agreement or encumbrance has been or will be made or entered into which would conflict with this assignment or sale.

May 14, 1991	s/Galen D. Knight
Date	Assignor
May 14, 1991	s/Terence J. Scallen
Date	Assignor

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

THE REGENTS OF THE UNIVERSITY
OF NEW MEXICO

Plaintiff and Counterdefendant,

vs. Cause No. CIV 99-577 JC/WWD

GALEN D. KNIGHT, an individual;
and TERENCE J. SCALLEN, an individual;

Defendants and Counterplaintiffs.

FIRST DECLARATION OF TERENCE J. SCALLEN, MD., Ph.D.

I, Terence J. Scallen MD., Ph.D., declare and state as follows:

1. I received a Bachelors degree from the College of Saint Thomas (1957), MD. from the University of Minnesota (1961), internship in Medicine at the University of Minnesota Hospitals (1961-1962), research fellow in the Department of Medicine at the University of Minnesota (1962-1965), and Ph.D. in Biochemistry from the University of Minnesota (1965). I was employed as a full-time faculty member at the University of New Mexico School of Medicine from September 1, 1965 until September 1, 1995 when I retired.

2. My duties as a faculty member included teaching, service, but primarily research. My research efforts were supported by numerous grants from the National Institutes of Health (National Institute of Arthritis and Metabolic Disease and the National Heart Institute), Sandoz Pharmaceuticals (now Novartis), and by several smaller grants, e.g., The Life Insurance Fund and the National Multiple Sclerosis Society.

3. At the time I retired I was Professor of Biochemistry (since 1974) and Professor of Medicine (since 1982). I was a consultant to Sandoz Pharmaceuticals (now Novartis) from 1980 until 1993. I have been acknowledged by Novartis as a key member of the team that discovered and developed the drug Lescol, which is presently on the market for the treatment of coronary heart disease. I am an author on approximately 100 peer-reviewed scientific articles.

4. Honors I have received included:

- Bausch and Lomb Science Medal 1953
- Postdoctoral Research Fellow, U.S. Public Hlth. Svc. (5F2-GM-130) 1962-1965
- Young Investigators Award, The American College of Cardiology 1969
- Invited Speaker, Eighteenth Nobel Conference on Derivatives of Mevalonic Acid, Stockholm, Sweden 1991
- Invited Speaker, Jacques Monod Conference on Lipid Flow in the Cell, Roscoff, France 1991
- Invited Speaker, British Biochemical Society, Warwick 1992
- Guest Associate Editor, J. Lipid Res. 1993-1994

5. Following my retirement on September 1, 1995, I received a letter-of-appointment for part-time teaching which was performed during the Fall of 1995. This

appointment was effective between September 1, 1995 until June 30, 1996. I moved to California in late April of 1996.

6. I am an Inventor on the Subject Inventions and Subject Patents, patent applications, CIPs, divisionals, etc. for the vitaletheine modulators (with Dr. Knight) and for the uses of beta-alethine (with Drs. Knight and Mann).

7. I received on or about October 10, 1998 from Judith Evans, patent attorney for the licensee, a copy of what was purported to be a prosecution file for a pending CIP application "Beta Alethine as Anti-Tumor Agent". This was the first prosecution file I had ever seen. While examining this file I noted that the Inventor Declaration (combined Declaration and Power of Attorney) included with this Application was one which I had signed on August 4, 1992. However, the application was not identical to the 1992 CIP application since a number of new claims had been added.

8. I began to wonder at this time (Fall of 1998) if the vitaletheine modulator applications might also have contained a Combined Declaration and Power of Attorney, signed in 1992 by the Inventors.

9. On May 14, 1999 I requested additional information from the Plaintiff's attorney, Mr. Stephen Slusher, regarding the 1992 CIP applications. On or a about May 22, 1999 I received from Mr. Slusher a letter (dated May 19, 1999), copies of three of the CIP applications, and also copies of the Combined Declaration and Power of Attorney documents, signed in 1992 by the Inventors, which were being used to authenticate both the vitaletheine modulator applications and the beta-alethine applications.

10. During the Summer of 1999 (July-August) I began to suspect that one or more of these declarations may have been used unlawfully in numerous patent applications, but particularly in US Patent 5,578,313. I discussed this matter with Mr. Mathew Kreeger (Morrison & Foerster, San Francisco) whom I retained for two specific purposes: 1) to

obtain complete prosecution files on three US Patents which had issued out, namely, 5,370,868, 5,643,966, and most significantly, on 5,578,313; and 2) to attempt to negotiate a settlement of the present litigation.

11. On September 27, 1999 I received the prosecution files referred to above. I then discovered that my suspicions were correct. My "Combined Declaration and Power of Attorney", dated August 10, 1992, had been used to falsely and probably fraudulently support an amended application which issued as US Patent 5,578,313, containing an amendment filed over three years later (November 6, 1995) changing all of the structures of the vitaletheine modulators.

12. This realization that my declaration had become false due to the amendment of this application by the University, without my specific knowledge or approval, occurred on or about September 27, 1999. I was justifiably horrified by this discovery.

13. I communicated this discovery to the Court on October 23, 1999 (Surreply Memorandum in Opposition to Plaintiff's Motion for Summary Judgment ... Counts I and II, at pages 4-6.

14. On or about October 20, 1999 I discovered that USPTO requires a supplemental oath or declaration to be made by the Inventors if the original application (in this case the 1992 CIP application on vitaletheine modulators in neoplasia) has had <u>any</u> changes, e.g., amendments, changes in the specifications, or changes in the claims. These supplemental declarations were not sought from the Inventors by the University for any of the applications of the vitaletheine modulator Inventions or the beta-alethine Inventions.

15. The requirement for supplementary declarations was also communicated to the Court on October 23, 1999 (Surreply Memorandum in Opposition to Plaintiff's Motion for Summary Judgment ... Counts I and II, at page 5).

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated this 25th day of February, 2000.

s/ Terence J. Scallen

Terence J. Scallen, MD., Ph.D.

[*Pertinent legible portions of Cover sheet from file wrapper for U.S. 5,370,868*]

December 6, 1994 Patent Number 5370868

SERIAL NUMBER	FILING DATE	424	7808	1502
07/928,725	08/13/92			

GALEN D. KNIGHT, ALBUQUERQUE, NM;
TERENCE J. SCALLEN, ALBUQUERQUE, NM.

CONTINUING DATA********
VERIFIED THIS APPLN IS A CIP OF
O7/549,440 07/06/90 ABN

FOREIGN/PCT APPLICATIONS********
VERIFIED

FOREIGN FILING LICENSE GRANTED 09/11/92
****** SMALL ENTITY *****

Foreign priority claimed			yes	X no	
35 USC 119 conditions met			yes	X no	
State or Country	Sheets Drwgs.	Total Claims	Indep. Claims	Filing Fee Received	Attorney's Docket No.
NM	23	69	3	$835.00	A2931C.CIP

ADDRESS
NIXON & VANDERHYE
1100 NORTH GLEBE ROAD
8TH FLOOR
ARLINGTON VA 22201

Title
THERAPEUTIC USE OF VITALETHEINE MODULATORS IN NEOPLASIA

NOTICE OF ALLOWANCE 5-16-94

s/EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500

[Inventor Declaration contained in the file wrapper for U.S. 5,370,868]

PATENT

Attorney's Docket No. A-2931C.CIP

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: (check one applicable item below)

X original
Design
Supplemental

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in part application do not check next item; check appropriate one of last three items.

National stage of PCT

NOTE: If one of the following 3 items apply then complete and also attach ADDED PAGES FOR DIVISIONAL CONTINUATION OR CIP.

Divisional
Continuation
X continuation-in-part (CIP)

INVENTORSHIP IDENTIFICATION

WARNING: *If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.*

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (*if only one name is listed below*) or an original, first and joint inventor (*if plural names are listed below*) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

THERAPEUTIC USE OF VITALETHEINE MODULATORS IN NEOPLASIA

SPECIFICATION IDENTIFICATION

The specification of which: (*complete (a), (b) or (c)*)

(a) X is attached hereto.

(b) Was filed on _____ as Serial No. ____ or Express Mail No., as *Serial* No. *not yet known* _____ and was amended on _____ (*if applicable*).

NOTE: *Amendments filed after the original papers are deposited with the PTO which contain new matter are not accorded a filing date by being referred to in declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, ate those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.*

(c) was described and claimed in PCT International Application No. _____ filed on _____ and as amended under PCT Article 19 on _____ (*if any*).

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37 , Code of Federal Regulations. § 1.56(a).

___ in compliance with this duty there is attached an information disclosure statement. 37 CFR 1.97.

PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT International application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign applications(s) for patent or inventor's certificate or any PCT international applications(s) designating at least one country other than the united States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(*complete (d) or (e)*)

(d) X no such applications have been filed.

POWER OF ATTORNEY

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (*List name and registration number*)

Jean A. Buttmi	Reg. 24,236
Martin P. Hoffman	Reg. 22,261
Albert Sopp	Reg. 19,996

(check the following item, if applicable)

____ Attached as part of this declaration and power of attorney is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s)

SEND CORRESPONDENCE TO	**DIRECT TELEPHONE CALLS TO:** (*Name and telephone number)*
Hoffman, Wasson & Gitler, P.C. Suite 522 2361 Jefferson Davis Highway Arlington, VA 22202	Martin P. Hoffman (703) 415-0100)

DECLARATION

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

Full name of **sole or first inventor** Galen D. KNIGHT
Inventor's signature s/Galen D. Knight
Date August 10, 1992 Country of Citizenship USA
Residence 3205 Arizona, N.E., Albuquerque, New Mexico 87110
Post Office Address Same

Full name of **second joint inventor,** if any Terence J. Scallen
Inventor's signature s/Terence J. Scallen
Date August 10, 1992 Country of Citizenship USA
Residence 7412 El Morro Rd., N.E., Albuquerque, New Mexico 87110

[Pertinent legible portions of Cover sheet from file wrapper for U.S. 5,578,313]

Patent Date NOV 26 1996 Patent Number **5578313**

Serial Number	**Filing Date**	**Class**	**Subclass**	**Group Art Unit**
08/317,548	10/04/94 Rule 60	514		1615

GALEN D. KNIGHT, ALBUQUERQUE, NM;
TERENCE J. SCALLEN, ALBUQUERQUE, NM.

CONTINUING DATA********
VERIFIED THIS APPLN IS A DIV OF O7/928,725 08/13/92 PAT 5,370,868 WHICH IS A CIP OF 07/549,440 07/06/90

FOREIGN/PCT APPLICATIONS********
VERIFIED

FOREIGN FILING LICENSE GRANTED 11/30/94
******SMALL ENTITY*******

Foreign priority claimed yes X no
35 USC 119 conditions met yes X no

State or Country	Sheets Drwgs.	Total Claims	Indep. Claims	Filing Fee Received	Attorney's Docket No.
NM	23	69	3	$904.00	181024

ADDRESS
THOMAS E. BYRNE
NIXON & VANDERHYE
8TH FLOOR
1100 NORTH GLEBE
ARLINGTON, VA 22201-4714

THERAPEUTIC USE OF VITALETHEINE MODULATORS IN NEOPLASIA

NOTICE OF ALLOWANCE MAILED
4/29/96

s/EDWARD J. WEBMAN
PRIMARY EXAMINER, GROUP 1500

[Inventor Declaration contained in the file wrapper for U.S. 5,578,313]

PATENT

Attorney's Docket No. A-2931C.CIP

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: (check one applicable item below)

X original
Design
Supplemental

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in part application do not check next item; check appropriate one of last three items.

National stage of PCT

NOTE: If one of the following 3 items apply then complete and also attach ADDED PAGES FOR DIVISIONAL CONTINUATION OR CIP.

Divisional
Continuation
X continuation-in-part (CIP)

INVENTORSHIP IDENTIFICATION

WARNING: *If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.*

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (*if only one name is listed below*) or an original, first and joint inventor (*if plural names are listed below*) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

THERAPEUTIC USE OF VITALETHEINE MODULATORS IN NEOPLASIA

SPECIFICATION IDENTIFICATION

The specification of which: (*complete (a), (b) or (c)*)

(a) X is attached hereto.

(b) ___ Was filed on _____ as Serial No. ____ or Express Mail No., as *Serial* No. *not yet known* _____ and was amended on _____ (*if applicable*).

NOTE: *Amendments filed after the original papers are deposited with the PTO which contain new matter are not accorded a filing date by being referred to in declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, ate those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.*

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(*complete (d) or (e)*)

(d) X no such applications have been filed.

POWER OF ATTORNEY

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (*List name and registration number*)

Jean A. Buttmi	Reg.	24,236
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(*check the following item, if applicable*)

____ Attached as part of this declaration and power of attorney is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s)

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SIGNATURE(S)

Full name of **sole or first inventor** Galen D. KNIGHT
Inventor's signature s/Galen D. Knight
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Post Office Address Same

Full name of **second joint inventor,** if any Terence J. Scallen
Inventor's signature s/Terence J. Scallen
Date August 10, 1992 Country of Citizenship USA
Residence 7412 El Morro Rd., N.E., Albuquerque, New Mexico 87110

[*Scallen letter to Quintana, UNM Patent Administrator, 06/05/96.*]

June 5, 1996.

Annabelle Quintanna
Patent counsel
1805 Roma NE #201
University of New Mexico
Albuquerque, NM 87131-6003

Dear Annabelle:

I have reviewed the Declaration regarding proposed new structures for the benzyl derivative of vitalethine as will [well] as a draft submitted by the University Contractor. [Unfortunately, this was not an independent evaluation since the Contractor was sent the Declaration instead of independently reaching his own conclusions.] The following comments are appropriate.

I find the evidence in support of the proposed sulfonate structure [taurine] underwhelming:

1. There is no chemical, physical or spectral evidence for the sulfonate functional group.
2. The chemical shifts of the methylene protons and the methylene carbon next to the putative sulfonate are not consistent with the presence of a sulfonate.
3. The "highly ionic character" of the putative sulfonate [taurine] is not supported by any scientific measurements. Minimally, there would need to be a titration curve giving the charge and pK for ionizable groups in the molecule.

4. There is no support for a sulfonate group based on the formation of suitable derivatives, e.g., sulfonamide or ester.

5. There is no infrared (IR.) evidence presented, either conventional or Ramen, for the presence of a sulfonate.

6. There is no mass spectral evidence presented for a sulfonate structure. It is my understanding from discussing this matter with Dr. Galen Knight that he has mass spectral data consistent with the original structure proposed by the inventors.

7. The elemental analysis obtained by the Inventors is not consistent with a sulfonate [taurine] structure.

It is of course possible that the Hauser group has obtained a compound which is different than that obtained by the Inventors. If that were the case, then extensive biological data would be required in order to establish its efficacy in the same tests as previously used by the inventors for the benzyl derivative.

[Parenthetically, it should e observed that the term "V3" has no chemical relevance to any structure and should be discarded in any discussions.]

Introduction of this "new" unproved and unevaluated compound by the licensee into this case and the striking of the benzyl derivative structure of the Inventors is, at best, foolish and, at worst, fraudulent and very much not in either the University's or the Inventors' best interests.

When you have read this letter please call me immediately to discuss these vital issues (619-676-1661).

Sincerely,

s/Terence J. Scallen

Terence J. Scallen, MD., Ph.D.
15220 Avenida Rorras
San Diego, CA 92128-4508

[*Scallen letter to Estes, UNM Counsel, 02/19/97.*]

February 19, 1997.

Charles N. 'Nick' Estes, Jr.
University Counsel
Scholes Hall, Room 152
University of New Mexico
Albuquerque, NM 87131

Dear Mr. Estes:

US Patent 5,578,313 was recently issued, bearing my name and the name of the University of New Mexico. This Patent, as published, contains serious falsifications and misrepresentations. Most glaring of all is the claim that several of the reported experiments were done with compounds which, in fact, we never used! I have previously notified you of these falsifications, prior to publication of the Patent, and I am shocked that the University has cooperated with the Licensee and/or his attorneys in continuing this misrepresentation. The damages to my personal scientific reputation, to the reputation of the University, and to the development of this Technology will be extreme unless immediate corrective action is taken.

I know the University of New Mexico stands for honesty and integrity in research and, therefore, will immediately cooperate fully in the filing with USPTO of a "correction sheet" incorporating these changes. In my conversation with the USPTO Examiner for this case he stated that this was the proper course of action.

Enclosed are four pages from the Patent with the appropriate corrections. The following comments relate to these corrections:

1) On the front page (Page 1), the application filed on October 4, 1994 has not been assigned. Apparently, there are questions regarding ownership, since the Inventors have been asked to assign this technology on several occasions. I would not have any problems with assignment to UNM, if the license were held by an individual who did not seriously misrepresent the technology and who did not falsify both chemical structures and our research results.

2) Page 1, the Figure shown is of no central interest. It is a comparison of tumor growth in old vs. young mice; neither group received treatment with vitalethine compounds. It is not the quintessential Figure in the applications! A better choice would be Fig. 22.

3) In Column 4 we never performed any of our studies with the taurine (sulfonate) compounds named here. This is utterly false and fraudulent. The elemental analyses and physical data in the Patent refer to the vitalethine compounds, not to the taurine (sulfonate) structures. In fact the taurine (sulfonate) structures are impossible, given the elemental compositions published by us previously in *Cancer Research* and also contained in the Patent.

> [You will note that both PAI and Dovetail have not presented any evidence for a taurine (sulfonate) functional group. Their results do not even meet the most basic criteria for chemical structure proof, since no elemental analyses were presented. Why has the elemental composition not been presented? Could it be that, if it were presented, it would show that both PAI and Dovetail synthesized compounds quite different from vitalethine? In addition, both Dovetail and PAI made serious departures from our

published procedures in their attempts to synthesize the vitalethine modulators.]

4) In Columns 37 and 38, as described above, none of our experiments were conducted with the taurine (sulfonate) derivatives shown.

5) The results in Table 1 have been falsified by changing the heading for Column 2 to B2 (a typo for Bz, which stands for the benzyl derivative). None of these experiments were conducted with the benzyl derivative. They were conducted with V_4. There are also falsifications contained in the legends for Figures 22 and 23; the benzyl derivative was used to treat myeloma mice, not the taurine (sulfonate) compound. I have incontrovertible documentary proof that this Table and these Figures legends have been falsified by the licensee and/or his attorney.

6) In Column 44, delete Claims 1 and 2. In Claim 3, use the structure of the benzyl derivative already correctly shown in Fig. 22. Again, none of the chemical or biological experiments in the Patent were conducted with the taurine (sulfonate) derivatives shown.

In spite of my objections, the unauthorized publication of this falsified Patent has produced damage to my professional reputation. I am prepared to do whatever it takes to seek appropriate remedies and redress. In order to maintain the ethical reputation of the University, I assume you will want to cooperate fully in the prompt preparation of a "correction sheet." Toward that end I expect a letter from you within the next week committing the University to this endeavor.

Thank you for your cooperation.

Sincerely,

s/Terence J. Scallen, MD., Ph.D.

Terence J. Scallen, MD., Ph.D.
Professor Emeritus

15220 Avenida Rorras
San Diego, CA 92128-4508

FAX: (619) 675-7504
Telephone: (619) 676-1661

[*Table 1* from Knight, G.D., Laubscher, K.H., Fore, M.L., Clark, D.A., and Scallen, T.J., "Vitalethine Modulates Erythropoiesis and Neoplasia", *Cancer Research* 54 at 5629.]

Table 1 *Vitalethine-induced survival in syngeneic Cloudman S-91 melanoma model*

Semimonthly regimen	100-day survivors/total	P values (two-tailed t test)
Saline	0/10	
Vitalethine		
3 fg/kg	2/10	0.151
10 fg/kg	3/09	0.0495
30 fg/kg	8/10	<0.0001
300 fg/kg	6/10	0.0017
3 pg/kg	4/10	0.0248
30 pg/kg	4/10	0.0248
300 pg/kg	2/10	0.151
3 ng/kg	6/10	0.0017
30 ng/kg	7/10	0.0002